

EXHIBIT 2F

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1 SUPERIOR COURT OF NEW JERSEY
 2 ATLANTIC COUNTY/CIVIL DIVISION
 3 DOCKET NO. ATL-L-6966-10
 4
 5 LINDA GROSS and JEFFREY GROSS, : STENOGRAPHIC
 6 Plaintiffs, : TRANSCRIPT OF:
 7 :
 8 v. :
 9 : - TRIAL -
 10 GYNECARE, ETHICON, INC., JOHNSON & :
 11 JOHNSON, and JOHN DOES 1-20, :
 12 Defendants. :
 13
 14 PLACE: ATLANTIC COUNTY COURTHOUSE
 15 1201 Bacharach Boulevard
 16 Atlantic City, New Jersey
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 18 DATE: February 4, 2013
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1 APPEARANCES (cont.'d):

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1 THE COURT: You can be seated.
 2 Ready to start? Bring the jury in.
 3 - - -
 4 (The jury enters the courtroom.)
 5 - - -
 6 THE COURT: You can be seated.
 7 Your next witness, Mr. Slater.
 8 MR. ANDERSON: Yes, Your Honor. Plaintiffs
 9 call Dr. Uwe Klinge.
 10 - - -
 11 PROF. DR. UWE KLINGE, after having been duly
 12 sworn, was examined and testified as follows:
 13 - - -
 14 THE CLERK: Would you state your full name,
 15 spell your last name for the record.
 16 THE WITNESS: My name is Klinge, Uwe.
 17 THE COURT: You can be seated.
 18 - - -
 19 VOIR DIRE - DIRECT EXAMINATION
 20 - - -
 21 BY MR. ANDERSON:
 22 Q Good morning, Dr. Klinge.
 23 A Good morning.
 24 Q Can you please tell the jury where you
 25 live?

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1 A I'm living in Montzen. That is a small village
 2 at the eastern part of Belgium. And this is about 10
 3 miles away from Aachen. This area is very close to the
 4 Netherlands, Germany, Belgium, where all these
 5 countries are coming together, and I'm living in this
 6 place.
 7 Q And did you come here from Belgium to
 8 testify in front of this jury here today?
 9 A That is correct.
 10 Q Dr. Klinge, please tell the jury your
 11 profession?
 12 A With the help of my CV, I started medical school
 13 in --
 14 Q First of all -- I'm sorry.
 15 First of all, tell them your profession.
 16 Are you an abdomen surgeon?
 17 A I'm an abdominal surgeon and a biomaterial
 18 researcher, including histology, pathology, with the
 19 focus of meshes in soft tissue -- in soft tissues,
 20 yeah.
 21 Q Before we get into the issues in this case
 22 involving Prolift, tell the jury a little bit about
 23 your background and your training and your education,
 24 please.
 25 A Okay. I started medical school in 1977 at the

1 Technical University in Aachen and finished it in 1983,
 2 in the shortest time. Their Technical University is
 3 one of the most famous centers in Germany, and one of
 4 the main topics of it is engineering. And it is one of
 5 the biggest institutes, for example, for textile
 6 engineering as well, which later on was a big advantage
 7 for me.
 8 So after passing medical school, I went
 9 to -- or I started residency at the surgical department
 10 at the University Hospital in Aachen. This hospital is
 11 one of the biggest buildings in size in Europe. And it
 12 is a major hospital in this area, attracting a lot of
 13 patients from Belgium and the Netherlands as well. I
 14 started residency there and learned the basic
 15 principles of surgery, passed several hundreds of
 16 operations. And after having done all this, usually --
 17 or you pass or I passed an examine, at some official
 18 office there. And afterwards, I got -- I became a
 19 specialist for general surgery. That was in 1993.
 20 Afterwards, I became oberartz, that is a
 21 function that is quite similar to being an attendant
 22 surgeon on call. That means that you're fully
 23 responsible for what your residents are doing there and
 24 you're responsible for a certain number of patients.
 25 Q Dr. Klinge, if I could just stop you there.

3382

1 You said that Aachen University was a
 2 leading textile and surgical implant facility.
 3 Where does Aachen University rank in terms
 4 of surgical mesh research facilities in the entire
 5 world?
 6 A In the moment, because of our work, the -- we are
 7 at the top of this -- in this field.
 8 Q And who is the top surgical mesh
 9 biomaterial science researcher at this top facility in
 10 the world?
 11 A I would have to say me.
 12 Q You talked about becoming a specialist for
 13 general surgery in 1993, and then you went up to 1999
 14 in terms of getting your oberartz, which allowed you to
 15 be an attending.
 16 My question is, during this time as you
 17 became a surgeon, did you begin to perform hernia
 18 surgeries?
 19 A Yes. Indeed, it is a necessary part for becoming
 20 a specialist of general surgery to perform about 100 of
 21 hernia operations there. And, therefore, I had to do a
 22 lot of hernia surgeries in the time period after
 23 becoming a specialist. And after becoming a specialist
 24 in the beginning of the '90s, there are an increasing
 25 number of operations used meshes. So, therefore, in

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1 this time period of the beginning of the '90s, we
 2 increasingly get aware of meshes to be used as
 3 reinforcement of the tissues.
 4 Q In the abdominal wall?
 5 A In the abdominal wall.
 6 Q Okay. Sorry for interrupting you. Let's
 7 go back to, I think you were up to 2000?
 8 A So this was the career as a surgeon. And in
 9 parallel, there is an academic career in Germany. And
 10 it started to make a first scientific work, usually you
 11 start during the medical school. And this was done by
 12 me in the department for biochemistry where I had a --
 13 had to look at the red blood cells, whether they are
 14 able to attract oxygen and to deliver this in the
 15 tissue. So I made some -- about for three years, I
 16 worked in this department and made a thesis so that
 17 afterwards, I was allowed to take the title of doctor.
 18 So this was the first step there. Then
 19 later in 1993, and I'm sure we will talk about later on
 20 about it, 1993 we start to work scientifically on this
 21 meshes, not least because of our experience with
 22 this -- with our patients. And then I started to work
 23 scientifically, and for the next seven years, and all
 24 this together allowed me to apply for the venia
 25 legendi. Venia legendi does mean that if you get this

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1 permission, then you're allowed to represent surgery in
 2 lectures for the students and all over the hospital.
 3 So I got this permission in 2000. To get
 4 this, you have to collect all your scientific work.
 5 You have to collect or to list all the publications.
 6 And then it's going to an internal board and to an
 7 external revision or reviewer. And then if they accept
 8 and said, okay, it's qualified enough, then you get
 9 this venia legendi and then you get the new title as
 10 privatdozent.
 11 Q What does that mean?
 12 A It sounds a little bit strange. I think, or I
 13 know that it's only available in Austria and in Germany
 14 till now, but we are used to it for 100 years. So it
 15 definitely means that you have shown that you're able
 16 to do some science successfully and that you're able to
 17 work as a professor. But it is not sufficient to be a
 18 professor. But if you get this title of privatdozent,
 19 then you have to still work on for the next five, six
 20 years. You have to collect your research project. You
 21 have to collect all this literature. You publish
 22 there. And after these five, six years, you can apply
 23 again, and then again an internal board, an external
 24 board. And then if they accept this, then you get the
 25 title of a professor.

3385

1 So this is the end of the academic career
 2 in Germany. And it took -- it was the end of a long --
 3 of a long trip of 28 years for me. So it was almost
 4 exactly after 28 years after I started to study in
 5 Aachen, then I got the title finally of the professor.
 6 And this was in -- so I have to look. It was in 2005.
 7 Yeah, in 2005.
 8 Q In terms of the specific work that you
 9 performed and the research and the publications that
 10 you were talking about, between 1993 and 2000, in order
 11 to -- I know I'm going to mispronounce it, but the
 12 venia legendi, in order to achieve that level, was that
 13 research that you did during those seven years
 14 specifically with regard to tissue response,
 15 biomaterial science and surgical meshes for the human
 16 body?
 17 A That is correct. And it started with our
 18 experience of hernia meshes or meshes in the abdominal
 19 wall, where we got aware that some of these patients
 20 have serious complications. They have a lot of wound
 21 liquid around these devices. Some of them have pain,
 22 some of them have infection, some of them has fistula
 23 formation to the bowels. So we have serious problems
 24 in some of these patients, and we got a little bit
 25 concerned. And we wanted to know what is the reason

3386

1 for this.
 2 If you made a revision operation of these
 3 patients and you are looking to these devices, during
 4 implantation, they are looking quite nice, very flat,
 5 very smooth, and you have a good feeling that it's now
 6 a very strong repair. But if you are looking after
 7 three months, after six months, they are completely --
 8 it's a stiff plate, they are integrated only in scar
 9 tissue and curled up and wrinkled. And we wanted to
 10 understand what is the reason for this change from the
 11 textile to this -- what we have seen in the OR. And
 12 there are hundreds of images showing what happens to
 13 these textile products after placing in the soft
 14 tissue.
 15 THE COURT: Counsel, we want to -- do you
 16 want to offer the witness as an expert?
 17 MR. ANDERSON: I had a little bit more, but
 18 I'm happy to.
 19 THE COURT: Well, it seemed to me he was
 20 going into the substance of his testimony as opposed to
 21 just qualifications at this point. So can we just
 22 stick to qualifications and then --
 23 MR. ANDERSON: Certainly.
 24 BY MR. ANDERSON:
 25 Q So you were talking about the work that was

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1 necessary for you to achieve this habilitacion and
2 venia legendi from 1993 to 2000.

3 Okay. We'll get back to some of that work.

4 Okay?

5 A Yes.

6 Q We will come back.

7 A Yeah, yeah, yeah.

8 Q So in 2000, what did you do? Let me ask
9 you this before we do that.

10 In addition to biomaterial science, tissue
11 response for surgical meshes during this 1993 to 2000
12 time period where you did all of this research in order
13 to obtain the venia legendi, did that also involve
14 histopathological review of this tissue response?

15 A Yes, exactly. It is an integrative part of these
16 investigations, to look at the soft tissues.

17 Q Please explain to the jury what
18 histopathology is as it relates to our bodies -- our
19 body's tissue response to surgical meshes like Prolift?

20 A So histology, histology is that you want to
21 analyze what happens to the tissues. And usually you
22 need a microscope to see this. Usually surgeons only
23 at the microscopical level and they saw what they can
24 feel and what they have in their hands. So to
25 understand this a little bit better, you need to use a

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1 microscope and to look a little bit more deeper to the
2 details. And that is histology. That is the science
3 of the tissues.

4 If there are some diseases or if there is
5 some injury and damage, then you have a pathology. And
6 you can learn from the pathology what is the disease in
7 the background, what is the reason for the injury.
8 And, therefore, it is necessary to look to the
9 histology and pathology to understand what happens in
10 the OR with these materials. It was an essential part
11 of this study.

12 Q And just in its most simplest form, during
13 these years from '93 to 2000, in all of this research
14 that you were doing, were you looking at the body's
15 response to polypropylene meshes in human tissue after
16 being implanted with surgical meshes like Prolift?

17 A That's correct. That is a part of it.

18 Q Okay. And then I see from your CV in 2000
19 you became the principal investigator of the surgical
20 department at Aachen University.

21 Just briefly explain that to the jury, if
22 you would?

23 A The other research projects dealing with the
24 meshes, and I'm the leader of all these projects, they
25 have an amount of money and work there that it has to

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1 be coordinated a little bit better. And we build up or
2 we increase the resources in our lab. And I was put in
3 charge to organize all this and to be responsible for
4 this work.

5 I just would like to point out, maybe in
6 the next time I sometimes mixed up I and we, I was told
7 that it is -- may be a little bit different here.

8 In science, it is only fair to say "we,"
9 because the work is done by a team, and so, therefore,
10 I very often will say "we." But, in fact, I'm
11 responsible for everything there, so if you want to
12 charge me, it is an I. So maybe -- yeah. So that you
13 have it correct, even if I say "we," it's...

14 Q Fair enough. Thank you.

15 And then in 2002 you became the specialist
16 for surgical intensive care medicine at Aachen
17 University surgical department; is that correct?

18 A That is correct. We have a -- yeah. We have an
19 own intensive care unit for -- in our surgical
20 department at that time, and I was working there for
21 several years. And I have to pass an examine for this
22 and then I qualified as a specialist for intensive
23 care, surgical intensive care medicine as well.

24 Q And then from 2003 to 2006, you were
25 assistant medical director of the entire facility.

3390

1 Can you please explain that?

2 A There has been two assistant medical directors or
3 vice chairmen in our department, and I was one of it.
4 So if the other two are not in the hospital, you are
5 responsible for everything. So everyone will know what
6 does it mean.

7 Q So in 2004, you became a specialist in
8 abdominal surgery. Briefly explain that to the jury.

9 A So a specialist in general surgery means that you
10 are -- that you know the standard operations and that
11 you can -- you're able to do them in full
12 responsibility. This visceral surgery, the specialist
13 for this means that you are able to perform advanced
14 surgical procedures. That means extended oncologic
15 resections, bowel resections, resections of the
16 esophagus or something like that and liver resection.

17 So you have to do another number of, but
18 now major operations, and then you have to pass an
19 examine and then you're allowed to do these operations
20 in full responsibility. And then you get the
21 specialist for visceral surgery. I don't know whether
22 it's here.

23 Q Is visceral surgery another way of saying
24 abdominal surgery?

25 A Yes.

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3393

1 Q And from 2006 to 2009, I see that you had a
2 cooperation with the Helmholtz Institute.

3 Just briefly explain, please, what work you
4 did for those three years with biomedical engineering
5 in cooperation with the surgical department,
6 biomaterial science and engineering.

7 A The main focus of the entire university, but as
8 well of the hospital, is the focus of medical
9 engineering. And, therefore, one part of the
10 University Hospital is this Helmholtz Institute. It
11 includes five, six different institutes. 90 percent of
12 the employees are engineers. So it is the bridging
13 between engineering and medicine. And I had the
14 opportunity to work there for three years.

15 Q After that, did you return to Aachen
16 University as the principal scientific investigator?

17 A It sounds a little bit difficult, but it's only
18 200 meters or 250 yards, I think. So I returned back
19 to the surgical department, because it was more easy to
20 coordinate this research activities then.

21 Q Were you the principal scientist
22 supervising these research activities in biomaterial
23 science research for surgical meshes to be implanted in
24 bodies, like the Gynemesh PS Prolift in this case?

25 A It didn't change since 2000.

3392

1 Q So that's true?

2 A And it's still there, yeah.

3 Q Now I'd like to talk a little bit about
4 your work between 1995 and 2005.

5 In addition to being an abdominal surgeon
6 with all the specialties that you have described and
7 all the different certifications that you have received
8 and being a principal biomaterial science investigator
9 in the surgical department looking at tissue
10 engineering and histopathology, in addition to those
11 things, now I'd like to talk about any work that you
12 may have done with outside medical device
13 manufacturers. Okay?

14 A Yes.

15 Q Can you please explain to the jury this
16 consulting work that you did with outside medical
17 device manufacturers using your expertise from 1995 to
18 2005?

19 A So as I've said, in 1993 we've got the problem
20 with these implants, and, therefore, we established a
21 comprehensive work on these materials for, first of
22 all, to define some requirements and then to study
23 them, what happens there. And if you want to study the
24 effects of these materials, you need to have a lot of
25 various materials to define the impact. And,

1 therefore, it was very, very helpful to have someone
2 who provides you with the material, with the suture
3 material, so that you can then test the impact of all
4 the different properties to the tissue. And this has
5 been Ethicon. And it started in 1994, where we, in a
6 close collaboration, studied the impact of various
7 material modifications on the soft issue.

8 Q And when you say "we," is that in
9 collaboration between you and your group in Aachen and
10 Ethicon in Norderstedt?

11 A Yes, yes. It is a large group. It is several
12 different institutes within the hospital of Aachen. It
13 is five, six people from the R&D department of Ethicon
14 Norderstedt. And it's been about ten surgical
15 colleagues which are all integrated into this field.

16 Q How extensive was the work that was done
17 during that decade, from 1995 to 2005, between you and
18 Ethicon?

19 A It was a very close collaboration, so we have a
20 lot of phone calls, because, in the beginning, we
21 wanted to define. We had to make a -- we had to define
22 the requirements for this material, and then we made a
23 lot of tests, about 20 different materials. And so we
24 permanently exchanged the results. There were working
25 meetings at least four times a year. We have the

3394

1 entire group from Norderstedt came to Aachen, and where
2 a whole day we have been discussing what we have done,
3 the results and what has to be done in future.

4 Q When you began this consulting relationship
5 with Ethicon, was this the first time that the
6 scientific community had begun to look at the tissue
7 response in humans to surgical meshes?

8 A It was not the first time. There are some single
9 investigations in the '80s. But it was the first time
10 that you want to create a comprehensive scientific
11 support for a medical device and to make a specific
12 design for a specific use. That was the first time.

13 MR. GAGE: Your Honor, just wondering if
14 we're still on voir dire or if we're kind of getting
15 more into the substance.

16 MR. ANDERSON: I'm just trying to get
17 through his credentials.

18 THE COURT: Okay. Then just stay away from
19 what his investigations discovered and just outline his
20 career, that's fine.

21 BY MR. ANDERSON:

22 Q Explain what you have done over the last 20
23 years in terms of -- strike that.

24 We heard a little bit about your
25 biomaterial science research and your looking into the

1 tissue response of surgical meshes like Prolift to the
 2 human body. And you mentioned histopathology.
 3 Tell the jury a little bit about your
 4 training in histopathology over these 20 years, just
 5 briefly.
 6 A The analysis of histopathology to foreign body
 7 materials, it's not a very simple question, even if
 8 I -- I'm asked to do it briefly. Because what we
 9 started to do to look to the soft tissues in 1994, I
 10 went to the department for pathology, and there was no
 11 one who could help us who could say that we knew how to
 12 quantify or qualify the histological implants or the
 13 cellular response to these materials. And they sent me
 14 away.
 15 And, fortunately, there has been a
 16 colleague who made his residence in surgery there
 17 before, so I know him. And he's a pathologist, Dr.
 18 Klosterhalfen. I think he's well known for everyone
 19 who is in this business. And he said, okay, I don't
 20 know it either, but let's try. And, therefore, in this
 21 year, in 1994, we started to establish the principles
 22 how to analyze the soft tissue reaction. And he knows
 23 a lot of different markers, and we together tested all
 24 these markers, whether they are helpful to
 25 differentiate between the good materials and the best

3396

1 materials. And that was established there, and you
 2 will find it in the publications, in the early
 3 publications, they focus on this principles how to make
 4 this analysis.
 5 And in the following years, we used this
 6 knowledge, we improved permanently, we looked at -- I
 7 looked at thousands of these stainings --
 8 Q By stainings do you mean --
 9 A Sections, histological sections. Where you look
 10 at tissue --
 11 Q Slides from tissue pathology?
 12 A Yes.
 13 Q Okay.
 14 A Where you have the soft tissue and the
 15 biomaterial and where you have to define what is the
 16 extent of inflammation and fibrosis there.
 17 Q Can I stop you right there?
 18 You mentioned fibrosis. So was part of
 19 what you were doing was looking at the body's responses
 20 to meshes that may cause fibrosis or scarring? Is that
 21 true?
 22 A Yeah.
 23 Q Shrinkage of the mesh once it's in the
 24 tissue?
 25 A Yes.

1 Q And the complications that result due to
 2 fibrosis, shrinking in the human body?
 3 A Yes.
 4 Q So this work in terms of biomaterial
 5 science, the tissue response and the histopathology and
 6 your experience as an abdominal surgeon who had
 7 implanted meshes, was this all being put together so
 8 that you could analyze the problems that were happening
 9 with patients with meshes?
 10 A This was our big advantage to combine all these
 11 three experiences. And you cannot separate this.
 12 Q Great. Have you published -- let me go
 13 back.
 14 The jury has heard what peer-reviewed
 15 literature means, so I don't want to go back through
 16 that, but have you published in the peer-reviewed
 17 literature?
 18 A Yes.
 19 Q How many publications do you have in the
 20 peer-reviewed literature?
 21 A You will find about -- more than 200
 22 publications, and I hope the number will increase.
 23 Q And how many of those relate directly to
 24 surgical meshes either for the abdominal wall or the
 25 pelvic floor?

3398

1 A More than 100 of it.
 2 Q How many times have those publications been
 3 cited as references by other authors in the scientific
 4 community?
 5 A Last time I looked, it was more than 2,000.
 6 Q So your work on surgical meshes in the
 7 literature has been cited by other scientists over
 8 2,000 times; is that correct?
 9 A It's highly recognized, yeah.
 10 Q Have you written books and published book
 11 chapters?
 12 A Several book chapters.
 13 Q How many?
 14 A 50, about 50.
 15 Q How many of those 50 related to the issues
 16 in this case, surgery involving mesh, biomaterials
 17 science and tissue response?
 18 A 45.
 19 Q 45 books and book chapters?
 20 A Book chapters.
 21 Q Yes.
 22 Have you been an invited lecturer to
 23 conferences?
 24 A Yes.
 25 Q Approximately how many times -- I see in

1 your CV that you've lectured over 200 times and 130
2 times as oral presentation as an invited lecturer.

3 So of those 330 times that you've given
4 lectures, approximately what percentage of those were
5 relating to the issues in this case, surgical mesh,
6 biomaterials and tissue response and the problems that
7 can happen in a human being as a result of those?

8 A It's about 90 percent or more.

9 Q 90 percent of the 330 times you've been
10 asked to speak?

11 A Yes.

12 Q Have you been asked to speak by Ethicon at
13 conferences?

14 A Yes.

15 Q How many times?

16 A Some dozens.

17 Q Dozens of times.

18 And do you continue to be an invited
19 speaker for Ethicon at conferences?

20 A Yes.

21 Q When was the last time you were invited by
22 Ethicon to speak at a conference for them?

23 A It was in the week of my deposition. So two days
24 later on I was asked to give a presentation for Ethicon
25 in Brussels, and the weekend I was asked to do a

3400

1 presentation in Munich for Ethicon, to present the
2 history of meshes, because in some regards, I represent
3 20 years of history of meshes.

4 Q Have you been invited to lecture to your
5 peers on pelvic floor meshes like Prolift?

6 A Yes.

7 Q How many times?

8 A About 10 to 15 times.

9 Q And the audience at these conferences where
10 you've been asked to lecture on pelvic floor meshes,
11 have there been gynecologists at the conferences?

12 A Yes.

13 Q Urologists at other conferences?

14 A Yes.

15 Q Urogynecologists at other conferences?

16 A Yes.

17 Q In fact, have you been asked by Ethicon to
18 speak to urogynecologists at their Norderstedt facility
19 regarding pelvic floor repair meshes and how they can
20 create problems in the human body?

21 A Yes.

22 Q Have you been a peer reviewer for
23 scientific journals?

24 A Yes.

25 Q Approximately how many different journals

1 per year are you a peer reviewer where you are looking
2 at your peers' submitted literature?

3 A It's varying a little bit between five and ten
4 different journals per year.

5 Q And how many different manuscripts do you
6 review per year, in other words, publications that have
7 been submitted, in order to determine whether or not
8 they should be allowed to be published in the
9 scientific literature?

10 A It's around 25 to 35 a year.

11 Q Do they relate to the fields of surgery,
12 biomaterials science, tissue reaction, histopathology
13 and wound healing?

14 A Most of it, yeah.

15 Q Have you received a number of grants over
16 the years?

17 A Yes.

18 Q The jury may have heard about NIH grants.
19 We're talking about grants for you in Germany.

20 What is a grant, just briefly?

21 A If you want to make a research project, it
22 usually costs money. And you need some resources,
23 personal resources consumers, and so you have to apply
24 to get the money. And usually this is reviewed. And
25 if it's accepted, then you get the resources and then

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1 you can start to work for it. And, therefore, a big
2 time or -- yeah. We spend a lot of time to apply for
3 these grants to get the money for our research. And in
4 Germany, it is the Ministry, it's the German Society
5 for Research where you can go to a hospital, and we
6 successfully got several grants, too, for our research.

7 Q Approximately how many grants have you
8 received over the years?

9 A About 20.

10 Q So approximately 20 times someone has
11 deemed your work to be important enough to fund it?

12 A Yes.

13 Q And how many of those have involved
14 surgical mesh, biomaterials science, tissue response
15 and histopathology of meshes like Prolift to be
16 permanently implanted in a woman's body?

17 A All except two.

18 Q Do you hold any patents?

19 A Yes.

20 Q How many patents do you hold?

21 A Seven.

22 Q Do they all relate to surgical mesh?

23 A Yes.

24 Q Have you served as an independent
25 court-appointed expert in Germany?

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1 A Yes.

2 Q On approximately how many occasions?

3 A It's about three dozen, four dozen.

4 Q So if you are -- three or four dozen, so

5 somewhere around maybe 30 or 40 times a court has

6 appointed you in Germany as an independent expert to

7 come in and give your opinions?

8 A Yes.

9 Q You talked a lot about your hernia surgery,

10 your abdominal surgery and all the other things you've

11 done. You aren't coming here today as a pelvic floor

12 surgeon, are you? I'm sorry. I asked the double

13 negative.

14 You don't perform pelvic floor surgery.

15 Correct?

16 A That is correct, yeah.

17 Q You're not coming in here as a

18 urogynecologist. Right?

19 A I'm an abdominal surgeon.

20 Q You are not a urologist. Right?

21 A No. That is right, I'm not.

22 Q I will try to do better. We will try to do

23 better.

24 You are not -- you are not a gynecologist.

25 Correct?

3404

1 A It is correct that I'm not.

2 Q So what is it about your background,

3 training, experience that you believe gives you an

4 expertise to talk to the jury today about a surgical

5 mesh like Prolift that actually is implanted by

6 urogynecologists?

7 A We have made extensive research, over 20 years,

8 to look what happens if you use meshes in the soft

9 tissue, what has to be considerate to get an optimum

10 device. That is the focus of all our research in this

11 field. And there is hardly anyone else who can -- who

12 has this experience of -- as we have.

13 Q By "we," do you mean you?

14 A Yes.

15 Q And I understand you're a humble person and

16 you're trying to give the "we" credit to others, but I

17 need to ask you now, because the jury is hearing from

18 you today, to put it simply, is there anyone else in

19 the world who has studied over the last 20 years and

20 published more articles, anyone who has done more work

21 than you in the area of surgical meshes for -- that

22 would be used for the abdominal wall or the pelvic

23 floor and done more research or studied the

24 biomaterials science, the histopathology and the

25 surgical implications for surgical meshes in the human

1 body?

2 A There is none.

3 MR. ANDERSON: At this time, plaintiffs

4 would offer Dr. Uwe Klinge as an expert in the fields

5 of abdominal surgery, biomaterial science, tissue

6 reaction and tissue engineering, histopathology for

7 surgical meshes in the human body.

8 MR. GAGE: Your Honor, we'll reserve cross.

9 THE COURT: Okay. The Court finds that the

10 witness is qualified to give his opinions to the jury

11 as an expert in those fields. You can proceed.

12 MR. ANDERSON: Thank you, Your Honor.

13 - - -

14 DIRECT EXAMINATION

15 - - -

16 BY MR. ANDERSON:

17 Q Did I approach you back in 2011 and ask you

18 to be an expert in this case?

19 A Yes.

20 Q Did I agree to pay you for your time?

21 A Yes.

22 Q Did I ask you to review an enormous amount

23 of materials and ultimately write an expert report in

24 this case?

25 A Surely.

3406

1 Q Let's talk about the materials that I, over

2 the course of that year-and-a-half, have sent to you

3 and that you've reviewed.

4 You've looked at over 500 Ethicon internal

5 documents. Correct?

6 A At least.

7 Q Representing hundreds if not a few thousand

8 pages?

9 A Yes.

10 Q Over 100 to 150 pieces of literature?

11 A That is correct.

12 Q Depositions of at least 30 witnesses, some

13 of them covering multiple days?

14 A Yes.

15 Q Numerous expert reports?

16 A Yes.

17 Q Have you looked at somewhere between 15 and

18 20,000 pages of documents?

19 A Yes.

20 Q Did I agree to pay you \$100 an hour for

21 travel and \$500 an hour for the work that you've done?

22 A That is correct.

23 Q And you've spent over 200 hours in the past

24 year-and-a-half helping me work on this case?

25 A That is correct.

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1 Q For all of the review that we just
2 mentioned, all of those documents and then writing a
3 68-page report; is that right? Something like that?
4 A Yes.
5 Q Dozens of references in that report,
6 preparing for and sitting for a two-day deposition,
7 coming here and preparing for trial and then speaking
8 here at trial today, have I paid you somewhere around
9 \$100,000 for that work?
10 A That is correct.
11 Q Do you believe that when you work for
12 someone that you should be compensated?
13 A That is fair.
14 MR. ANDERSON: Your Honor, before I begin
15 with the next portion, I was wondering if it would be
16 okay if I have the bailiff pass the -- allow the mesh
17 to be passed around to the jury.
18 THE COURT: Sure. If there's no objection
19 from counsel.
20 MR. GAGE: What is it?
21 MR. ANDERSON: The product, the Prolift.
22 THE COURT: Show Mr. Gage what you're going
23 to do, just in case he does have an objection.
24 BY MR. ANDERSON:
25 Q Since we're going to be talking about the

3408

1 biomaterial science and specifically we're going to
2 spend the rest of our time talking about Gynemesh PS
3 and Prolift for the jury. Okay? So I just wanted to
4 give them an opportunity to pass this amongst
5 yourselves quickly, as long as you need to take, but
6 then we'll move along with your questioning. Okay?
7 A That's fine.
8 THE COURT: One of the jurors wants a
9 break, so as soon as we're done passing the mesh, we'll
10 take a short break.
11 MR. ANDERSON: Yes.
12 THE COURT: You will have this in the jury
13 room with you when you deliberate. You'll also have
14 stacks of evidence that have been admitted, so you will
15 have a lot of documents and other things with you in
16 the jury room at the end of the case. I just want you
17 to know that.
18 Okay. We can take the jury out for a
19 minute.
20 - - -
21 (The jury leaves the courtroom.)
22 - - -
23 THE COURT: Take a break.
24 - - -
25 (A recess was taken from 10:05 a.m.

1 to 10:35 a.m.)
2 - - -
3 THE COURT: Let's argue this motion about
4 tomorrow quickly.
5 It's the expert argument for tomorrow?
6 MR. MAZIE: For Hinoul?
7 MS. JONES: I don't know which one you're
8 talking about.
9 THE COURT: You filed a motion on Piet
10 Hinoul. Right?
11 MR. MAZIE: Right.
12 THE COURT: To prevent him from referring
13 to any research or articles. It seems to go even
14 further and suggests he can't refer to any manuals or
15 brochures, but you're not trying to suggest he can't
16 discuss the label or the patient brochure. Right?
17 MR. MAZIE: No. It's really the
18 literature, Your Honor. He's not an expert. He wasn't
19 even in the company back in 2004, 2005 and 2006. He
20 didn't join until 2008. And, in fact, apparently he
21 didn't come to the United States until --
22 THE COURT: Well, it may not even be an
23 issue. Ms. Jones may not be intending to take him
24 through the medical literature. I don't know if you
25 know yet, or if you want to wait --

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1 MS. JONES: Your Honor, he was the
2 corporate designee on this issue and has been asked a
3 number of questions already, as Your Honor may recall,
4 about what happened, you know, before he got there.
5 I don't intend to go through the literature
6 with him as I would with an expert. Part of his job
7 responsibilities, though, have been evaluating the
8 risks and benefit of the product. And he is certainly
9 familiar with, and has written as part of his
10 responsibilities, reports analyzing the risk and the
11 benefits and looking at the various studies that are
12 out there. I think since he did that in the course of
13 his day-to-day work and responsibility, that he's
14 entitled to testify about that and to the extent that
15 it's included within those reports that he's got.
16 MR. MAZIE: Judge --
17 THE COURT: I don't think the objection is
18 to his testifying about risks and benefits or any
19 report that he wrote. I think it's just to putting a
20 learned treatise up on the --
21 MR. MAZIE: It goes further than that,
22 Judge. He's a fact witness. Just because he's
23 designated for our purposes to give us information at a
24 deposition, we're now at trial. And at trial, he's
25 either a fact witness as to what he actually did, and

1 he wasn't there. I mean, he didn't even come until
2 over two years after it's implanted in Linda Gross. So
3 he's certainly not an expert. He hasn't been
4 designated as an expert. So we can put that aside.

5 He can talk about what he did in 2004, 2005
6 and 2006, but he didn't do anything.

7 THE COURT: Well, you know, I always have
8 this two-way street thing going on. The bottom line is
9 you put in a lot of evidence of things that occurred in
10 2008, 2009, 2010, and Mr. Slater argued repeatedly that
11 the Ethicon people had admitted that everything that
12 they knew in -- that everything that came out in 2009
13 they knew in 2005.

14 So, I mean, it's like when your witnesses
15 are on the stand, they're saying you shouldn't be
16 putting on post-surgical events, information. When
17 they're on the stand, now you want to say they
18 shouldn't be putting on post?

19 MR. MAZIE: They can do it, but not with
20 this witness is my point. My point is, he's a fact
21 witness. If they want to bring somebody in from 2005
22 to say this is what we looked at, this is how I drafted
23 this, they can do that. It's not for this witness is
24 our point. He's not an expert. He's a guy that came
25 later on after all these -- everything that happened in

3412

1 this case happened. And they certainly are more than
2 welcome to bring in anybody that was involved in those
3 decisions. I don't have a problem with that. I mean,
4 I thought we made that clear in the brief.

5 It's that Dr. Hinoul is not an expert and
6 he was not there, so he's not a fact witness. He can't
7 testify to facts that happened then because he's a fact
8 witness. That's the point. He can certainly go into
9 things back and forth, but the fact that he's now
10 analyzed it in 2009 or 2010, I don't know how that
11 affects what was done back in 2005.

12 MS. JONES: First of all, what he has done
13 in the course of his day-to-day responsibilities now is
14 done as a fact witness. In terms of other aspects of
15 this, Your Honor, he's already been cross-examined
16 by -- on a significant number of things that relate to
17 pre-2006. Certainly we are entitled to have him
18 explain his answers and go through that. And the
19 plaintiffs chose to go with him.

20 MR. SLATER: Judge, we don't object
21 obviously to the extent I asked Mr. Hinoul questions,
22 obviously he can be asked by counsel about what I asked
23 him. And I kept it very narrow. I did not ask him one
24 question about the IFU. I didn't ask him any questions
25 about the brochures or the warnings or anything about

1 that. Zero. And our position is he wasn't -- with
2 regard to warnings and things like that, he shouldn't
3 be talking about what was done in '04 or '05, because
4 that's factual testimony beyond the scope of what he
5 was asked when we put him on the witness stand within
6 the scope of his corporate designation, which is for
7 our purposes.

8 If he wants to talk about warnings that
9 were provided in '08, '09 and 2010, I mean, I suppose
10 he could, but then he's going to start implicating all
11 the issues the defense doesn't bring in, because those
12 warnings are all the warnings that -- the warnings that
13 existed when he came to the company, that was right
14 when they were changing all their warnings, when the
15 public health notifications were coming out and they
16 were reacting to that, when the FDA was telling them to
17 change their warnings. So that factually he's at the
18 company in the point in time when the defense doesn't
19 want to bring that in, so -- and those warnings
20 post-date Linda's surgery, so I wouldn't expect them to
21 ask him any questions about warnings for those reasons.

22 You know, I asked him primarily questions
23 about the design intent, which was within his
24 designation, and the complications the company knew of,
25 because he was designated from medical affairs to talk

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1 about the known complications. I mean, we've been
2 through the transcript. That's the -- pretty much what
3 he was asked about. There may be a question here or a
4 question there about a few other things, but that's
5 pretty much it.

6 And I studiously stayed away from many
7 areas that I didn't want to open the door on, because I
8 didn't think it was appropriate to give him those
9 questions. And factually he's not at the company in
10 that time period. So as far as the literature, the
11 other part of the motion, obviously, is just that they
12 have an expert, you know, presumably, who is going to
13 talk about the literature, so --

14 THE COURT: Well, she's already said he's
15 not going to talk about the literature.

16 MR. SLATER: Okay. I might have...

17 THE COURT: You have asked him about the
18 risks and benefits, or at least the risks and the
19 complications. They certainly are going to be able to
20 ask him about the benefits to counter that. But this
21 isn't within the scope of your cross. That's not the
22 issue. The issue is -- and I realize the brief wasn't
23 fashioned that way, but the issue is what can he
24 testify to.

25 He is a corporate representative. Can she

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1 put him on the stand to go through the IFU? Does he
2 have to have been there when that IFU was published for
3 her to go through the IFU with the jury with him? I
4 don't think so. That's not expert testimony to say
5 this is what it said, this is what we warned about. It
6 would be nice to have a person from 2005, but then you
7 didn't call the person from 2005, you called him. And
8 now they're going to call him.

9 MR. SLATER: We videotaped her. It was
10 Charlotte Owens.

11 MR. MAZIE: We asked for her to come in.

12 MR. SLATER: And David Robinson, we
13 videotaped him, too. He's not available either.

14 MR. MAZIE: So we have technically called
15 them. I mean, you know, that was implicit -- the
16 reason there's a corporate designee is for our
17 purposes, not for theirs. It's to make -- because we
18 need someone with the most knowledge to educate
19 themselves, and that was discovery.

20 MR. SLATER: He was only designated on
21 specific issues, and I focused on only really, you
22 know, the design intent and the complications. I
23 really didn't go beyond that with him, I mean, other
24 than a few straggling questions on --

25 THE COURT: Well, I'm assuming that her

1 outside the scope of his ability to testify, you can
2 object. Let's wait and see where it goes. If she
3 wants to put the IFU up there and go through and this
4 is what was in and this is what your company did warn
5 about, I'm going to let her use him for that purpose.
6 That I don't think is improper. I think you asked him
7 about the IFU -- well, you might not have asked him
8 about the IFU, but you definitely have asked him, you
9 know, things that were relative to 2005, or at least
10 you argued that they were at the time.

11 MR. SLATER: On the complications,
12 absolutely. Knowledge of complications, that's what I
13 asked him about. I didn't ask him one question about
14 what they warned about on purpose.

15 MR. MAZIE: Can I ask for clarification?
16 With regard to the primary emphasis of the motion,
17 which really was going through the literature --

18 THE COURT: Well, the primary thing was
19 literature, which she said he's not going to do, except
20 that to the extent that he wrote a report, he may
21 testify as to what his report was. But he's not going
22 to testify to this is a learned treatise from so and so
23 and this is what the finding was and this is what the
24 statistics from that report were and that's what they
25 mean. That's going to be confined to her expert.

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1 focus is going to be on the design intent, the
2 complications and the benefits.

3 MR. MAZIE: My only concern is how does
4 that cross over and does it cross over into expert
5 testimony from a guy who wasn't even there when this
6 was happening? That's what we wanted to bring to Your
7 Honor's attention. They're going to have Dr. Murphy
8 tomorrow, I think. He's going to go into all of this.
9 Then they are going to bring in someone who wasn't even
10 at the company until two years after Linda has it
11 implanted in her, and he's really giving the same
12 testimony. I have no problem with him going into what
13 he did in '08, '09, '10, '11, '12 to today. But to go
14 back and do what Dr. Murphy is doing and to maybe go
15 through why it's safe, because he studied on it after
16 he came to the company, is really expert testimony.
17 It's inappropriate.

18 MR. SLATER: And cumulative. I mean, we
19 dropped witnesses. We dropped Dr. Margolis in strict
20 adherence to Your Honor's rulings that we couldn't have
21 two people talk about causation. So we dropped someone
22 who would have been a very persuasive witness on that
23 issue.

24 THE COURT: If his testimony is repetitive
25 or cumulative, you can object. If the questions are

1 And the primary thrust of your motion was
2 devoted to learned treatises. And you have won on that
3 part, won by concession, because the defense has agreed
4 that they weren't going to use him for that.

5 MS. JONES: Thank you.

6 THE COURT: So when it comes to where he's
7 testifying, if you think he's going beyond the bounds,
8 then you're just going to have to object as we go
9 along. We're just going to have to rule, but, you
10 know, just to say to him, is this what was in effect at
11 the time, he's a corporate rep, even though I
12 understand what you're saying, that he should be
13 confined to a period of time, but he can, as the
14 designee of the company, stand here and say this was
15 our warning in 2005.

16 MR. MAZIE: Okay.

17 THE COURT: Now, he is subject to cross
18 about whether they changed it or not. Well, we'll deal
19 with that bridge when we get to it.

20 MR. SLATER: That was my only concern,
21 obviously.

22 THE COURT: But at this point, he'll be
23 testifying as to, you know, whatever he knows. And as
24 a corporate representative, he does know what the IFU
25 was. He knows what an IFU is. He knows what a patient

1 brochure is. Can he testify that in 2005 we did this
2 for this reason or that reason? Probably not. But he
3 can say, this is what the known benefits were at that
4 time, and this is what the known downsides were, based
5 on the literature that exists within the company. I'm
6 going to allow him to do that. All right?

7 MR. SLATER: We should wait and see if it's
8 cumulative and deal with it?

9 THE COURT: Anything -- yeah, obviously. I
10 don't expect him to be a duplicate of their expert in
11 any way. I mean, there's going to be an overlap,
12 because the jury has to hear it from a company
13 representative as to what the company knew, too. I
14 mean, you can't -- I think they have to have some
15 company representative. And if, as they've
16 represented, they can't bring in some of these other
17 people, then -- I'm going to let them have some leeway
18 with that. I'm just going to let you know that.
19 They're not going to go into literature, they're not
20 going to be cumulative, and we'll see where it goes.

21 MR. SLATER: Fair enough.

22 THE COURT: And if you feel that we're
23 going over those boundaries, object question by
24 question.

25 MR. SLATER: Thank you.

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1 THE COURT: We'll proceed.

2 - - -

3 (The jury enters the courtroom.)

4 - - -

5 THE COURT: Continue with the witness.

6 MR. ANDERSON: Thank you, Your Honor.

7 BY MR. ANDERSON:

8 Q If you could put up slide 1, please.

9 Dr. Klinge, you had indicated to the jury
10 before the break that you'd written over 100 articles
11 that relate directly to surgical meshes in the human
12 body. Correct?

13 A That is correct.

14 Q Clearly we're not going to go through those
15 100 articles or anywhere close to it, but I did want to
16 bring to the jury's attention six of your important
17 ones, okay?

18 A Yeah, that is okay.

19 Q In 1998, PLT0268, what was that study about
20 in terms of mesh must adapt to the physiology? Briefly
21 explain that to the jury.

22 A So that the conception of this work was to define
23 the requirements to design a mesh and to test whether
24 it changes the reaction of the tissues. And with the
25 help of the people from Hamburg-Norderstedt, this was

1 the first result. So we were able to produce a
2 modified mesh that is adapted to the physiological
3 requirements. And in this study, we could show that it
4 really improves the tissue integration.

5 Q And just be a little more specific if you
6 would, please, about what you mean by, to define the
7 physiological requirements of the mesh?

8 A The basic principle of this mesh was that we
9 found out that most of the older meshes have been
10 oversized. They are much too strong in comparison to
11 what is needed in the abdominal wall. Therefore, we
12 could reduce the amount of material down to 30 percent.
13 And that means that we were able to enlarge the pore
14 size. And this mesh has a reduced amount of work and
15 has large pores of more than 3 millimeter.

16 Q When you say "this mesh," you're not
17 talking about the Prolift mesh, you're talking about
18 the mesh that you were studying. Correct?

19 A That was this new development.

20 Q Okay. Go ahead.

21 Okay. Then in 1998, you had another
22 publication. Briefly explain to the jury what was
23 brought to the scientific world as a result of that
24 publication?

25 A One major concern of these meshes that is our

3422

1 experience during the operations was the strong scar
2 formation and the shrinkage and the folding of these
3 meshes. So, therefore, we wanted to test whether these
4 new meshes with the larger pores really can reduce the
5 amount of shrinkage. And in this preclinical study, we
6 could show that both are of polypropylene, but now we
7 have a mesh material with lower weight, with larger
8 pores, and in fact, the degree of the extent of
9 shrinkage could be reduced significantly.

10 Q And just to be clear, when we're talking
11 about larger pores, the jury just handled the Prolift
12 mesh. We're talking about the holes that go throughout
13 the mesh; is that correct?

14 A That is correct.

15 Q And then in 1999 --

16 THE COURT: Well, wait. Back in the 1998,
17 it says 30 percent to 50 percent PP mesh shrinks.

18 Was the mesh shrinking between 30 and 50
19 percent or was that a reduction in the amount of
20 shrinkage? What does that 30 to 50 percent mean?

21 THE WITNESS: The one mesh, the bad mesh
22 shrank up to 50, whereas the better showed only a
23 shrinkage of only 30 percent.

24 THE COURT: Go ahead.

25 BY MR. ANDERSON:

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1 Q To clarify that point -- thank you, Your
2 Honor -- it's not actually the mesh itself shrinking,
3 it's the scar around the mesh that's pushing it
4 together; is that correct?

5 A Yes, that is absolutely correct. But in our
6 terms and in our discussions, we, some years ago,
7 stopped to make this differentiation, because everyone
8 knows that polypropylene does not shrink itself. It's
9 a wound contraction.

10 Q And when we talk about contracting mesh or
11 bunching mesh or shrinking mesh, we're talking about
12 the same thing, just different words. Correct?

13 A Yes.

14 Q Speaking of the foreign body reaction, what
15 did you publish in 1999, Dr. Klinge?

16 A So our next point was that we wanted to know what
17 happens to this reaction of the tissue to the foreign
18 body materials after long term, whether it sometimes
19 ended or not. And in this study of human explants, we
20 could show that there is an ongoing inflammation at the
21 interface between the fiber and the surrounding tissue.
22 And it never ends. It's going to be a little bit
23 smoother over the years, but you always have some sort
24 of inflammation there. And it is like a chronic wound
25 which can persist for, yeah, lifelong.

1 have a scar plate around the mesh and lead to shrinkage
2 and complications in patients if those pores were not
3 greater than 1 millimeter? Do you have an opinion?

4 A Yes.

5 Q And did they? Were they aware of this?

6 A Yes. Of course they were aware of it, because
7 that -- one of the reasons that we -- or one of our
8 advantages were that we published all these details so
9 that the scientific community has free access to all
10 these results, all manufacturers have free access of
11 all these results. So the data came maybe one, two
12 years before. But in the moment where this is
13 published, everyone has free access to this
14 information.

15 Q Thank you, Dr. Klinge.

16 And then just two more here I want to go
17 through. 2005, lightweight, large pore concept.

18 What was that a publication regarding?

19 A All these findings together were just summarized
20 in this article, and it was named as the lightweight,
21 large pore concept. And the various aspects are much
22 more -- they were summarized in this article, and this
23 was a term, it's a concept.

24 Q So is it fair to say that between 1995 and
25 2005, you and your group in Aachen brought to the

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1 Q And then in 2002 you published some other
2 findings. Explain that to the jury briefly.

3 A The basic question was what was the reason for
4 this scar formation? Was it some cells, was it some
5 inflammation or -- and in this study, we could identify
6 that the pore size, it's the outstanding critical
7 component that defines whether you have a lot of scar
8 formation around the mesh. And, therefore, pore size
9 is -- mainly determines how good a mesh will be
10 incorporated and how safe it is in the last
11 consequence. And there we saw that if you have small
12 pores with less than 1 millimeter in diameter, usually
13 all this area is filled just by scar tissue, what we
14 don't want to have.

15 Q And did Ethicon fund that study in 2002?

16 A Yes.

17 Q So am I correct, Dr. Klinge, that by 2002,
18 Ethicon knew that in order to prevent mesh shrinkage
19 and the problems associated with it, you needed to have
20 pore sizes greater than 1 millimeter; is that correct?

21 A It's correct. All these findings have been
22 extensively discussed together at our working meetings.

23 Q And do you have an opinion as to whether or
24 not Ethicon knew by 2002 that pore sizes, these holes,
25 would have fibrotic bridging, scarring across the hole,

1 scientific world the idea of tissue reaction to
2 surgical meshes and how you would measure it?

3 A Yes.

4 Q Brought to the scientific world the fact
5 that polypropylene meshes can shrink if you don't have
6 the proper design requirements?

7 A That is correct.

8 Q Brought to the scientific world that there
9 is a foreign body reaction to surgical meshes and it
10 will have a chronic inflammatory response, chronic
11 wound, that the design of the mesh may be able to
12 reduce?

13 A Absolutely.

14 Q And in 2002, did you, you and your
15 colleagues, bring to the scientific world for the first
16 time the idea that all of this work could be -- that
17 some of these problems would be avoided if you had pore
18 sizes that had 1 millimeter in diameter throughout the
19 course of the mesh?

20 A That has been the main message of this work and
21 many presentations following and before.

22 Q Was the purpose for doing this work in
23 order to try to improve patient safety?

24 A Yes.

25 Q Was the purpose of this work to try to help

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1 manufacturers design better meshes for the area of the
2 body where they were going to be placed?

3 MR. GAGE: Objection, leading.

4 MR. ANDERSON: I'll withdraw it.

5 BY MR. ANDERSON:

6 Q What was the purpose of this work other
7 than the safety in terms of the design for
8 manufacturers to be able to have this knowledge?

9 A It was proven by our work that it was possible
10 that defining the requirements, designing a better
11 mesh, studying it, that this can improve the tissue
12 response to these mesh materials and improve the safety
13 of the patient. And that was later on, and in these
14 years as well, there -- it was -- we added a lot of
15 clinical studies to show this. It was not only
16 preclinical work, but all this together confirmed for
17 many, many, many times that it is an advantage. And,
18 meanwhile, large pore meshes in Germany and in Europe,
19 it's outstanding.

20 Q Okay. Doctor, I'm going to ask you about a
21 couple of opinions. And I want to let you know that
22 any of the opinions that you state here to the jury and
23 before this Court today, according to New Jersey law,
24 have to be stated to a reasonable degree of scientific
25 or medical probability.

3428

1 You don't have to use those words, just can
2 we assume that if you're going to offer opinions, that
3 it is stated to a reasonable degree of medical or
4 scientific probability, unless you tell us otherwise.

5 Fair enough?

6 A That is fair.

7 Q After your review of tens of thousands of
8 pages of documents, deposition testimony, your 20 years
9 of work in the field and your ten years of work with
10 Ethicon, Dr. Klinge, do you have an opinion as to
11 whether or not Gynemesh PS in Prolift is safe to be
12 permanently implanted in a woman's pelvic tissue?

13 A Yes, I have an opinion.

14 Q And what is that opinion?

15 A It is not a safe design and it never had a chance
16 to be.

17 Q To be safely implanted in a woman's pelvic
18 tissue?

19 A Yes.

20 Q Do you have an opinion as to -- strike
21 that.

22 What is the general basis of that opinion
23 that Gynemesh PS in Prolift could never be safely
24 implanted permanently in a woman's pelvic tissue?

25 A The structural disadvantage of this mesh is that

1 you have rather small pores that are even made smaller
2 by some filaments crossing these pores. You have a
3 complete collapse of pores if you placed it under
4 mechanical strain. And this together leads to an
5 incorporation of the entire device into scar formation.

6 And that means by maturing of the scar shrinkage, that
7 the entire area of the mesh gets integrated into the
8 scar plate. And in the area of pelvic floor, this is
9 disastrous in regard to the function of the organs to
10 the dynamic of the structures in the pelvic floor.

11 Q Do you have an opinion, Dr. Klinge, as to
12 whether or not Ethicon was aware, prior to the Prolift
13 launch in March of 2005, of these problems?

14 A No doubt.

15 Q Dr. Klinge, you were telling the jury
16 earlier about these years that your group in
17 Norderstedt would have meetings and things like that
18 with the folks at Ethicon Norderstedt.

19 Do you recall that?

20 A Yes, yes.

21 Q At any of the meetings prior to the launch
22 of Prolift in March 2005, were there discussions about
23 Ethicon's idea of putting mesh into a woman's pelvic
24 floor?

25 A We never have been involved in the development of

3430

1 the Prolift, but it was -- I had a discussion with
2 Brigitte Hellhammer who --

3 Q Hold on.

4 Brigitte Hellhammer?

5 A Brigitte Hellhammer.

6 Q Was she an Ethicon employee from
7 Norderstedt?

8 A She was an employee and working at the R&D
9 department in Norderstedt, and she was part of this
10 group that regularly came to Aachen to discuss all
11 these results. And in 2000, she told me that there
12 is --

13 MR. GAGE: Objection.

14 MR. ANDERSON: Admission.

15 MR. GAGE: May we approach?

16 - - -

17 (The following occurred at sidebar:)

18 MR. GAGE: Your Honor, I object to the
19 witness on the basis of hearsay of providing an out of
20 court statement. And I wouldn't normally approach just
21 for that, but I figure this is a good to time to
22 approach on a bigger issue.

23 This is an expert witness who has been
24 designated solely as an expert witness. His
25 interactions with Ethicon obviously formed part of the

1 basis of his expertise and it's just historical fact of
2 what his job function is. So for that reason, I
3 thought it was appropriate not to object and let the
4 witness get into this. But it appears that where we're
5 headed now is a factual historical recitation by the
6 expert of what Ethicon -- of his personal interactions
7 with Ethicon as to what they knew and when they knew
8 it. And as an expert witness and solely designated as
9 such and not designated as a fact witness, I would
10 object to the witness going in that direction.

11 MR. ANDERSON: It's an admission by Ethicon
12 as to the fact that they were going to put these meshes
13 in the pelvic floor. He was their consultant at the
14 time. He was their expert consultant at the time. He
15 talked about all of the work that he did with them in
16 terms of trying to improve the design of various
17 things, and what he's about to tell this Court and this
18 jury, if Your Honor will allow it, is that when they
19 told him that they were going to do that, he said then
20 you better use all these principles that we've been
21 working on for the last many years if you're going to
22 put it in the pelvic floor. Then we're going into the
23 e-mail showing that they didn't listen to him.

24 THE COURT: I'm going to allow the fact
25 testimony as well as the expert testimony. He had

3432

1 factual interactions with them. I can't -- certainly
2 someone can testify as both a fact witness and an
3 expert witness. And I can't believe that -- well, it's
4 not that I can't believe it, but I think it's obvious
5 from the beginning that he's been called both as an
6 expert and because he previously had been a consultant
7 for Ethicon. That's been mentioned several times.

8 I'm going to allow it. This is an
9 admission. It's not hearsay. And your objection is
10 overruled but preserved for the record.

11 - - -

12 (The sidebar ended.)

13 - - -

14 BY MR. ANDERSON:

15 Q Let's reorient ourselves to where we were.

16 I had asked you if in any of your meetings
17 as a consultant for Ethicon whether or not the idea
18 that Ethicon was thinking about using surgical meshes
19 in the pelvic floor was brought to your attention at
20 one of these meetings.

21 Do you remember where we were in our
22 testimony?

23 A Yes, yes.

24 Q Okay. And you were telling the jury about
25 that meeting that you had with Brigitte Hellhammer?

1 A Yes.

2 Q Please start over or continue in that.

3 A Certainly. In 2000, she told me that it was
4 planned to use meshes for the reinforcement of the
5 pelvic floor. And I told her that, in this case, they
6 should adopt the principles that we developed the years
7 before to define the requirements, to make a design and
8 to focus on large pore mesh constructions, that they
9 should use these principles to avoid damage by other
10 structures.

11 Q And when you're talking about requirements,
12 you told her about that it needs to adapt to the
13 physiology of the area where they're going to place it?

14 A Yeah. But it has to be defined for the pelvic
15 floor. We did it just for the abdominal wall, but it
16 has to be defined for.

17 Q So the work that you had done with Ethicon
18 up at that point, you had defined the requirements for
19 the abdominal wall. Is that what you're saying?

20 A Yes.

21 Q But it had not been defined for the pelvic
22 floor for putting mesh down there. Correct?

23 A Yes, correct. But it should have been done, yes.

24 Q Did you explain to her that it would be
25 unsafe to do that if you hadn't defined these

3434

1 requirements?

2 A Yes.

3 Q Out of all of the depositions and the
4 documents reviewed, could you tell whether or not she
5 actually followed your advice? Did they in fact follow
6 your advice? Did they use these principles when they
7 designed Prolift?

8 A Obviously they did not, because the Gynemesh PS
9 or the Prolift does not show these structural
10 requirements. What we found out was essential.

11 Q In order to be -- you mean essential in
12 order to be permanently implanted in a woman's pelvic
13 tissue?

14 A Yes. And to be safe and to not make this scar
15 tissue response.

16 Q If we could look at the next slide, please,
17 Uri.

18 And this is --

19 Dr. Klinge, you have seen these e-mails; is
20 that correct?

21 A That is correct.

22 Q I believe the jury has seen these as well.

23 July -- June of 2003, an e-mail from Michel
24 Cosson to Scott Ciarrocca.

25 Who is Michel Cosson?

1 A He's one of the inventor or promoter of the
 2 Prolift.
 3 Q From your review, you understand Scott
 4 Ciarrocca was the Ethicon R&D team member that was the
 5 head of the Prolift project?
 6 A That is correct.
 7 Q E-mail, "The problems are more erosion,
 8 retraction. It is possible to have a recurrence, but
 9 it is usually due to a retraction of the mesh and the
 10 arms of the mesh are still left in place in those
 11 cases."
 12 And then the second e-mail, the e-mail from
 13 Ophelie Berthier to Zenobia Walji, May 10, 2004, you've
 14 seen that as well. Correct?
 15 A Yes.
 16 Q And in that e-mail, it says, "I know you're
 17 working on the new mesh materials with Gene and I'd
 18 like to share with you the inputs of Prof. Jacquetin
 19 and Dr. Cosson."
 20 And you know that Prof. Jacquetin is who?
 21 A He's the other inventor of this procedure.
 22 Q "Their main concern is now the shrinkage of
 23 the mesh, which may lead to pain, dyspareunia...indeed
 24 now they have tremendously improved the technique,
 25 lowered the erosion rate, what needs to be improved is

3436

1 the shrinkage of the mesh (in this case, Gynemesh
 2 Soft)."
 3 Do you see that?
 4 A I see it, yeah.
 5 Q These e-mails in 2003 and 2004, are they
 6 significant to your opinions in this case?
 7 A Yes. But the contents of these meshes --
 8 messages is not really surprising, because they just
 9 form out what was the fear what will happen. So at
 10 that time point, yeah, they should stop and study it.
 11 Q Stop the project, study the problems?
 12 A Yes. Would be most appropriate.
 13 Q Did they do that?
 14 A No.
 15 Q If we could see the next slide, please.
 16 Before we do that, if we could go back.
 17 These e-mails, you said your meeting with
 18 Brigitte Hellhammer was in 2000. Correct?
 19 A Yes.
 20 Q Then the e-mail on the left is 2003.
 21 Correct?
 22 A Yes.
 23 Q And then this one is 2004?
 24 A Yes.
 25 Q So this one is two years before the Prolift

1 is launched?
 2 A That is correct.
 3 Q Indicating these problems?
 4 A Yes.
 5 Q And this is a year before Prolift was
 6 launched indicating these problems. Correct?
 7 A That is correct.
 8 Q You were still a consultant with Ethicon in
 9 2003-2004. Correct?
 10 A That is correct.
 11 Q After this meeting in which you warned
 12 Brigitte Hellhammer about the problems if they didn't
 13 use the right design for something that was going to go
 14 into a woman's pelvis, did they come to you and say, we
 15 have got problems with erosion and retraction, can you
 16 please help us on this, Dr. Klinge?
 17 A I was never contacted in this field.
 18 Q When an e-mail comes from the people who
 19 invented the TVM technique a year before the launch
 20 indicating shrinkage, pain, dyspareunia, what needs to
 21 be improved is shrinkage, did they come to someone who
 22 had published on shrinkage and ask him to help them?
 23 MR. GAGE: Objection.
 24 BY MR. ANDERSON:
 25 Q You?

3438

1 MR. GAGE: No way the witness can know
 2 that.
 3 THE WITNESS: That it --
 4 MR. ANDERSON: Let me ask the witness.
 5 BY MR. ANDERSON:
 6 Q Did they come to you and ask you that?
 7 MR. GAGE: Your Honor, that wasn't the
 8 question. The question was, did they go to anyone.
 9 THE COURT: He's rephrasing whether they
 10 came to him.
 11 MR. ANDERSON: Yes, ma'am. Sorry.
 12 BY MR. ANDERSON:
 13 Q Did anyone come to you when they became
 14 aware of these problems with Gynemesh PS in the Prolift
 15 a year before the launch?
 16 A No, they didn't come.
 17 Q Had they come to you, would you have been
 18 willing to use the work that you'd been putting in for
 19 five years to try to help them avoid these problems?
 20 A Of course.
 21 Q Show the next document, please.
 22 You reviewed this document as well, Dr.
 23 Klinge?
 24 A Yes.
 25 Q The jury has seen this. This is an Ethicon

1 expert meeting in 2006.

2 What's your understanding as to why Ethicon
3 was having this meeting with inside consultants and
4 outside consultants in June of '06?

5 A This meeting was done because of these problems,
6 they are looking for better materials. And, therefore,
7 they invited all these people who have some experience
8 there to think about this.

9 Q To try to replace the Gynemesh PS mesh in
10 Prolift?

11 A Yep.

12 Q And this is a year after launch?

13 A Yes.

14 Q June of 2006. Correct?

15 A Two years after the e-mails.

16 Q And down below, you see J. Holste and
17 Brigitte Hellhammer.

18 Do you see that?

19 A These are two of the colleagues that are
20 regularly at our meetings in Aachen.

21 Q Well, in fact, Brigitte Hellhammer, she's
22 the woman that you had this conversation with at these
23 meetings in 2000 about the problems that could occur if
24 they didn't design Gynemesh PS right. Correct?

25 A That is the woman I talked with.

3440

1 Q You see the other participant in this is
2 Dr. Klosterhalfen who you said was a colleague of yours
3 for the last 20 years?

4 A Yes.

5 Q Also an Ethicon consultant. Correct?

6 A Yes.

7 Q And if we could see the next slide, please.

8 Under the meeting minutes that -- regarding
9 what Prof. Klosterhalfen told the group, I'd like to
10 talk a little bit about that first line, under
11 "Biological response to surgical mesh," where it says,
12 "Huge surface area of meshes, in other words, more than
13 300 meters of suture material."

14 Do you see that?

15 A Yes, I see it.

16 Q Dr. Klinge, did you make the calculations
17 of how much suture material is in this Prolift total,
18 if we were to unravel it and string it end to end, how
19 much suture material is in this product?

20 A If you stick to the same size, it is about
21 300-400 meters. That means about 400 yards.

22 Q So if you were unravel this, there is 400
23 yards, four football fields worth of polypropylene
24 woven into that; is that correct?

25 A That is correct.

1 Q When he says even after 20 years the tissue
2 is still reacting to the mesh, is that what he's
3 talking about, reacting to these four football fields
4 of suture material?

5 A Yes, that is correct.

6 Q Let me ask you this.

7 If someone comes in front of this jury and
8 says it's sufficient that we have 50 years, 50 years of
9 usage of polypropylene sutures in the human body,
10 therefore, we knew the Prolift would be okay in a
11 woman's pelvis, what would you say to that, Doctor?
12 A This is not sufficient to state this, because we
13 don't have, for example, polypropylene meshes like
14 Prolift for 50 years. We don't even have them for the
15 abdominal wall for 50 years. We only have some sutures
16 that are there in 50 years. So it mainly depends on
17 the configuration of this polypropylene. So any
18 statement just saying this polymer is safe or not safe,
19 it doesn't meet the point. It only depends in what
20 form this polymer is implanted in the body.

21 Q Does it depend on where it's going to be
22 implanted in the body?

23 A And where, of course, yeah.

24 Q Does it depend how much of it is going to
25 be implanted in the body?

3442

1 A All this is correct. And then you have to look
2 to the function. So you have to study it for every
3 configuration, for every function, for every indication
4 whether it fulfills the requirements. So, therefore,
5 it is essential to define, to design and then to study
6 it.

7 Q Is it also essential to know what the
8 design, for instance, the pore sizes, will be if you're
9 going to place a polypropylene mesh in a woman's pelvic
10 tissue for the rest of her life?

11 A There are countless further studies showing that
12 there are good polypropylene meshes and there are bad
13 polypropylene meshes, and that you can show the
14 difference in the tissue response and in the clinical
15 behavior and the clinical outcome. So there is a huge
16 amount of literature showing that there can be better
17 polypropylene meshes and polypropylene meshes with a
18 higher risk. So any statement to say polypropylene is
19 a good guy or a bad guy, yeah, it is not helpful.

20 Q You have to put it in context; is that
21 correct?

22 A Yes.

23 Q Now, you're not telling the jury that
24 polypropylene mesh, surgical mesh, could never at any
25 point in history be safe in a woman's pelvis; is that

1 correct?

2 A No. That is the same absolute statement that is
3 not appropriate. So there may be some times some
4 polypropylene structure that can be used in the pelvic
5 floor, but it has to be designed, it has to be shown
6 that it is like this. And in the moment, I don't know
7 any.

8 Q Have you seen one for the last 20 years
9 that would be polypropylene mesh appropriately designed
10 for a woman's pelvic floor?

11 A No.

12 Q The next line, if you could, please, Uri,
13 "Fibrosis is responsible for complications in mesh
14 usage."

15 So the next thing that Prof. Klosterhalfen
16 said after he was talking about these 300 meters of
17 suture material, it says, "Fibrosis is responsible for
18 complications in mesh usage."

19 Fibrosis, that's the scarring you're
20 talking about that can occur around meshes?

21 A That is correct.

22 Q And the amount of scarring that you get,
23 will that be dependent upon the mesh design?

24 A Yes. It depends from the amount of the material,
25 from the mesh design, from the surface and from the

3444

1 pores.

2 Q Okay. And then he mentions foreign body
3 reaction.

4 Let's just talk briefly with the jury about
5 what happens when our bodies have a foreign invader.

6 Next slide, please.

7 A So if you -- if you're injured by a foreign body,
8 so if you get a splinter into your finger, then
9 immediately the body tries to make a defense system
10 there to destroy and to eliminate this foreign body.
11 It is done by some local cells. They are building a
12 wall around this foreign body. And they are attracting
13 further cells, helping them. You are aware of this
14 phenomenon because you are feeling the swelling, you
15 are getting -- you feel some pain, you see the red skin
16 around it. And all this is the acute inflammation if
17 you get a foreign body, a splinter, in your hands. And
18 if you get two, or these two splinters will be
19 integrated into this acute inflammation.

20 So after one week, two week, the body may
21 recognize that it is impossible by these small cells to
22 remove this foreign body. Then it will go to a chronic
23 inflammation. That means that you have a wall of
24 inflammatory infiltrate around these foreign bodies,
25 and outside of this, scar formation. And this scar may

1 build up a border between the neighboring tissues and
2 this foreign body. And this is a situation that
3 persists lifelong, as long as the splinter or the mesh
4 remains in the body. So this is a permanent situation
5 there. You have an increased remodeling, the cells are
6 going and coming, but you have this huge amount or this
7 amount of scar tissue as a border between this foreign
8 body and the neighboring tissues.

9 Q And how is the amount of scarring related
10 to the amount of the foreign body?

11 A It's quite clear, the bigger the foreign body,
12 the bigger the inflammation. And the bigger the
13 inflammation, the bigger the scarring. That can
14 clearly be shown, and this is true for many diseases as
15 well, not only for foreign bodies.

16 Q When you were talking about scarring,
17 especially when it comes to the scarring that forms
18 around Gynemesh PS, once a scar --

19 A -- ever -- always a scar. There is no way to --
20 by the body to remove this.

21 Q So when we're talking about these foreign
22 bodies, explain to the jury about this inflammatory
23 process and the scarring as it relates to the diagram
24 you see in the middle, if you could just explain the
25 diagram and then explain from your standpoint why this

3446

1 is important when it comes to surgical meshes?

2 A You see in this image a cross-section of the
3 sutures, two sutures are coming directly to you, and
4 there is a cross-section. So the circle in the middle,
5 that should be the suture --

6 Q Dr. Klinge, would that be like if we're
7 looking at the end of the mesh and we're looking at the
8 fibers coming right at it?

9 A Yeah. Or when you cut it. When you cut it
10 through, then you will see it like this.

11 Q Okay. Go ahead.

12 A And every filament is surrounded by this
13 inflammatory infiltrate and by this fibrotic capsule.
14 And if these are -- if you have a large distance
15 between these two filaments, then the space in between
16 can be filled by fat tissue or what is there in this
17 area by the normal physiological tissue. But if these
18 filaments are going close together, then there will be
19 some distance where all this together, the two
20 splinters, will be integrated into one wound altogether
21 will be circulated by scar tissue and even the space in
22 between will be filled by scar.

23 Q And is that space filled between, is that
24 what the jury has heard about bridging fibrosis?

25 A The space in between the filaments, that is the

3447

3449

1 pore. And if this is filled by scar tissue, this is
 2 what we would call or we call -- that is the bridging
 3 fibrosis.
 4 Q And, again, when you were talking about if
 5 the fibers are far enough apart, it just has the scar
 6 or the granuloma around each one, what is that distance
 7 that there has to be, based upon your 20 years of work,
 8 when it comes to these pores?
 9 A For polypropylene, at least it has to be
 10 1 millimeter to avoid this filling of the pore by scar
 11 tissue. If you don't want to have it, you have to take
 12 care that the filaments are -- that the distance
 13 between the filaments is more -- even far more than
 14 this 1 filament.
 15 Q And I know you said before that your work
 16 from 2000 on with Ethicon, they were aware of this
 17 1 millimeter requirement. Correct?
 18 A This is correct. This has been published, and
 19 Prof. Klosterhalfen just refers -- he's -- yeah. He
 20 repeated these results of these years where we studied
 21 it.
 22 Q He repeats it at this expert meeting where
 23 they're trying to look at the problems with Gynemesh
 24 PS?
 25 A Yes.

3448

1 Q So the jury has heard small pore, large
 2 pore, they've heard words like macroporous,
 3 microporous. Forgetting the words for a moment, what's
 4 the important thing for this jury to know in terms of
 5 whether or not a pore will be large enough to prevent
 6 fibrotic bridging, scar plate, shrinkage and
 7 complications for a patient? What is that distance?
 8 A The main message is it is critical, the pore size
 9 is critical for the outcome, and it should be at least,
 10 as you stated, 1 to 2 millimeters.
 11 Q This will allow this fatty tissue to grow
 12 in?
 13 A And then you have a flexible mesh heading off
 14 these scar plate that, when it's contracted, it's
 15 coming -- it's becoming stiff and like leather, so you
 16 don't want to have this.
 17 Q And you have felt explanted mesh and what
 18 it feels like to have this scar wrapped around the
 19 fiber that has to be taken out of a patient. You've
 20 felt that. Correct?
 21 A Yeah. We have collected in our department,
 22 meanwhile, more than 500 explanted meshes from humans.
 23 And Prof. Klosterhalfen, he has, meanwhile, more than
 24 4,000 of these. And if you look to these explants,
 25 many, not all, but many of them are looking very, very

1 stiff, like leather.
 2 Q Next slide, please.
 3 At the end of this June 2006 expert meeting
 4 in Norderstedt, where Ethicon was looking at the
 5 problems with Gynemesh PS and looking to replace it,
 6 what were these -- what does this section, "Unmet
 7 clinical needs," tell you, Dr. Klinge? Is that
 8 significant to your opinions?
 9 A There -- it was the definition of the major
 10 problems. And if you remember the e-mails from 2003
 11 and 2004, they mainly take up the message again. So,
 12 in the center, what has to be done was to design
 13 material with no shrinkage, fibrosis reduction and
 14 severe contraction. And this was the highest priority.
 15 So it was very clear what should have been done. And
 16 this was expressed in this table in 2006.
 17 Q Let's go to the next slide, please, Uri.
 18 2007, a year later. Another expert meeting
 19 in Norderstedt. Correct?
 20 A It is correct, yes.
 21 Q Many of the same participants. Correct?
 22 MR. GAGE: Objection, Your Honor.
 23 BY MR. ANDERSON:
 24 Q Does this have many of the same
 25 participants --

3450

1 THE COURT: There's an objection.
 2 MR. ANDERSON: Oh.
 3 - - -
 4 (The following occurred at sidebar:)
 5 MR. GAGE: This meeting comes six or seven
 6 or eight months after Linda Gross's surgery. So in
 7 terms of this particular expert and in terms of what
 8 the company was discussing, et cetera, it's post-dating
 9 the surgery, and we would object to it on that basis.
 10 MR. ANDERSON: This is the scientific
 11 development, or lack thereof, of making any changes to
 12 the Gynemesh PS despite the fact that they repeated to
 13 see problems. It shows a lack of this company doing
 14 anything from one year to the next to the next. They
 15 continue to sell and market a product that had been
 16 told by this expert for years, you can't do this. It's
 17 a problem. They were told --
 18 THE COURT: But they can't -- first of all,
 19 we're not into a punitive phase where we're talking
 20 about that they continued to do something they knew was
 21 wrong.
 22 Second, other than that, what does this --
 23 other than their bad conduct post her surgery, what
 24 does this add?
 25 MR. MAZIE: It goes to Dr. Hinoul's

1 admission that they knew everything in the beginning.
 2 So anything that was discussed there is a reiteration
 3 of everything they already knew. And it's just proof
 4 of what they knew early on. He's already said we knew
 5 everything, every complication, every risk.

6 THE COURT: You can ask him about what was
 7 discussed at the meeting as long as you can tie it into
 8 this was already known in 2005.

9 MR. ANDERSON: Absolutely, it will be, Your
 10 Honor. And, again, it's already in evidence, the part
 11 I'm going to show.

12 THE COURT: Okay.

13 MR. ANDERSON: Thank you.

14 - - -

15 (The sidebar ended.)

16 - - -

17 BY MR. ANDERSON:

18 Q Put the slide back up, please.

19 We were talking about the fact that these
 20 are the same participants.

21 And what's your understanding of why this
 22 meeting was happening almost a year later?

23 A Almost the same participants. It's the same
 24 problem, they are still looking for a better material.

25 Q And did you see the PowerPoint that was

1 A Scar tissue, if it matures, it is losing
 2 20 percent of the water, and, therefore, it is getting
 3 closer together. And it -- if there is a mesh in
 4 between, it will shrink together, it will push
 5 together, it will fold it. And, therefore, if you have
 6 smaller pores, you will have more scar tissue, where
 7 you will have more shrinkage.

8 Q If we could look at the next slide.

9 The unmet needs here again almost a year
 10 later, 2007, another expert meeting. It says, "The
 11 following summary of unmet needs generated June 2, 2006
 12 was again confirmed without any adding."

13 Is that significant to your opinions in
 14 this case, Dr. Klinge?

15 A Yes, yes.

16 Q Why?

17 A At the top was again confirmed. So this is a
 18 copy and paste. Nothing has changed. And there was no
 19 information what really has been done to improve the
 20 configuration of the mesh.

21 Q Okay. Now that we've talked about the work
 22 that you've done about pore size, now that we've talked
 23 about Ethicon's knowledge about pore size prior to
 24 launching Prolift, I would now like to focus the jury's
 25 attention on the pore size and the pore geometry of the

1 presented by one of these individuals, I think it's
 2 Kirsten Spychaj? Did you see the PowerPoint
 3 presentation that she gave at this meeting?

4 A Yes, I've seen it.

5 Q Uri, if we could show that. I believe the
 6 jury has seen it.

7 MR. ANDERSON: This is P0753. I believe it
 8 is already in evidence, Mr. Gage.

9 MR. GAGE: Your Honor, just the same
 10 objection as I repeated just a second ago.

11 THE COURT: The objection is preserved for
 12 the record, Counsel.

13 MR. GAGE: Thank you.

14 THE COURT: You can proceed.

15 MR. ANDERSON: Thank you.

16 BY MR. ANDERSON:

17 Q "Factors related to mesh shrinkage, what do
 18 we know? A review of literature and internal studies."

19 "Pore size. Small pore meshes, less than
 20 1 millimeter, lead to fibrotic bridging," which we were
 21 discussing with the jury where it scars across these
 22 holes. Correct?

23 A Yes, that is correct.

24 Q "Increased shrinkage."

25 What does that do once it covers the holes?

1 Gynemesh PS in this mesh. Okay?

2 A Yes.

3 Q Next slide, please.

4 On the left, I wanted to bring up a photo
 5 that the jury saw last week from your colleague, Dr.
 6 Muhl's testing.

7 That's an arm, arm number 3 of a Gynecare
 8 Prolift total. Correct?

9 A Yes, that's correct.

10 Q And then what are we seeing on the right
 11 there, Dr. Klinge?

12 A On the right you see this mesh in higher
 13 magnification, and it is converted into a black/white
 14 image. And all these black structures represents the
 15 filaments. And you see that there are a lot of
 16 different pores, so spaces in between the filaments,
 17 here is a larger one, here are a smaller one and here
 18 are a lot of very, very small one. So when you implant
 19 this into the tissue, then the body reacts with a
 20 foreign body reaction, sends the cells and sends the
 21 scar tissues around these filaments.

22 So after incorporation and implanting this
 23 in humans, then you will see that a lot of these
 24 filaments get surrounded by these foreign body
 25 reaction. And what we found out in many, many, many

1 studies is, in these very small pores there, there --
 2 these are completely filled with scar tissue. And you
 3 need a huge difference or distance between the
 4 filaments.

5 And at this image, you see the structural
 6 problem of this mesh, because you see that in almost
 7 all of these pores, there are crossing some other
 8 filaments and they are bringing the scar formation into
 9 the pores. So that means that you have a significant
 10 reduction of really large pore areas that are free of
 11 scar tissue.

12 And this is the -- this can -- or this
 13 explains very well why would this structure after
 14 integration into tissue you have a problem with
 15 extended scar formation, because all this area will be
 16 integrated into scar tissue, and then you have here
 17 pores that are at the limit. If there is something
 18 changing through these pores, again, even this area
 19 will be surrounded by scar tissue.

20 Q You mean any changes --

21 A Any changes of these pores will increase the risk
 22 for scarring reaction.

23 Q So if minimal stress is placed on the mesh
 24 and the pores begin to collapse, it's even worse?

25 A Yeah. So in regards to the risk for scar

3456

1 formation and shrinkage and all these complications
 2 there, it maybe would have been better not to have
 3 these crossing filaments. But it has to be tested,
 4 because it has a lot of consequences to the
 5 biomechanical of all these things that has to be
 6 studied there, but here you see that is the main
 7 problem in regard to the clinical outcome. These are
 8 the crossing filaments, the crossing bars or whatever
 9 you like to name them.

10 Q And as we were looking at those
 11 photographs, the diagrams where you could see the end
 12 of the fibers with the granulomas around it?

13 A Yes.

14 Q Will there be scarring around each and
 15 every fiber of polypropylene throughout this entire
 16 piece of mesh?

17 A If you are looking with a microscope, you will
 18 see around every fiber at every area, you will see some
 19 inflammatory tissue around and some scar formation
 20 around. And in the smaller pores, you will see that
 21 they are filled by scar tissue. You will not see
 22 significantly amount of fat tissue in these pores, and
 23 that makes it stiff. So that is --

24 Q And leads to shrinkage?

25 A And shrinkage and other consequences of excessive

1 scar formation in soft tissue.

2 Q If someone were to come before this jury
 3 and say that pore size of 75 microns is sufficient in
 4 order to avoid scarring, in order to avoid scar plates,
 5 in order to avoid shrinkage, what would you want this
 6 jury to know, if someone stands before them and says
 7 75 microns instead of 1,000 microns is safe?

8 A I've recognized that there is a discussion in all
 9 the many documents about these 75 microns. This
 10 derives from the publication from my friend, Parviz
 11 Amid who was living in Los Angeles, and he was the
 12 first in 1997 who thought about pore size and proposed
 13 a classification of hernia meshes based on pore size.

14 But his focus was the risk for infection,
 15 because at that time, there were textile structures
 16 with some pores in comparison to some mesh materials
 17 without any pores. And we knew that they have an
 18 increased risk for infection. So, therefore, he said
 19 if you have pores of more than 75 microns, you have a
 20 lower risk of infection than if you don't have them.
 21 That was the basic reason for this. 75 microns. The
 22 size of the filament is around 90, 85.7 microns.

23 Q The filament, just one of the polypropylene
 24 fibers, it's already 95 microns?

25 A Every line here has a width of 90 microns. So we

3458

1 are talking about pores that are smaller, as every line
 2 here.

3 Q Can you find a pore that is 75 microns in
 4 size even in the knotting?

5 A Yes. You have to look -- to measure it and look
 6 precisely whether it really fits the 75, but from all
 7 what we know is a pore of 75 microns, this is filled
 8 not even by scar formation, just but -- by the
 9 inflammatory infiltrate. And -- but it never will be
 10 filled by fat tissue. So it is not a good cutoff to
 11 define a good pore from a bad pore. But, furthermore,
 12 it is not adequate to say a mesh with one pore size.
 13 You never have a mesh with one pore size. You see in
 14 this figure very clear that you have a huge variety.
 15 You have big pores, you have small pores. And there is
 16 no mesh without these pores of 75 microns, because you
 17 have these bindings, you have these knots. So,
 18 therefore, it is necessary to measure it and the
 19 variety of all these pores as well. But the cutoff of
 20 75, it's not predicting the risk of scar formation.
 21 It's meaningless.

22 Q Was that a classification in the late '90s
 23 that was classifying the -- you mentioned for the jury
 24 the older, heavier weight, small pore meshes?

25 A Yes. It was written at that time because we

1 started later on to produce these large pore meshes
2 with 3 millimeter and 5. So he didn't have it at that
3 time.

4 Q So he didn't have the large pore,
5 lightweight meshes in order to look at and determine
6 what the proper pore size was?

7 A Yeah. But he even didn't look to the tissue
8 response to the bridging fibrosis. That was not a term
9 he was looking at. He was mainly focused on infection.

10 Q And with your publications from '98, '99,
11 2002 forward, was the scientific community then aware
12 of the necessity of greater than 1 millimeter pores in
13 order to prevent this bridging?

14 A There was a permanent discussion that we need a
15 revised classification of this, because as you said,
16 most of the meshes meanwhile have pore size that are
17 far beyond, and it was not considered any longer as a
18 critical cutoff.

19 And, therefore, we proposed or we changed
20 or we -- no. We give a proposal of the new
21 classification that predicts the risk for this bridging
22 fibrosis later on.

23 Q Okay. So if someone were to come in front
24 of this jury and say that 1 millimeter pore size,
25 Klinge's work, 20 years of this information, we don't

1 minutes.

2 But before we do, based upon the testing
3 that you did and the results that he had from that
4 test, what percentage of Gynemesh PS would be covered
5 in fibrosis or scar tissue?

6 A It's almost 75 percent.

7 Q 75 percent of this would be covered in scar
8 tissue as a result of the pore size?

9 A If you placed this in the abdominal wall in a
10 plane fashion, if you plane it in a three-dimensional
11 fashion, by every bending, the pore size will go even
12 down. And if you play -- if you apply some sort of
13 tension there, you will see a deformation of the pores,
14 because the polypropylene itself is not an elastic
15 material. It is just -- any elongation is just done by
16 deformation by the pores. That means they will become
17 smaller, and, therefore, the percentage of bridging
18 fibrosis will increase even more. So if you place it
19 tension free in the abdominal wall in a plane area,
20 75 percent is the correct.

21 Q I want to talk about even before any
22 tension is placed on this mesh, do you have an opinion,
23 based upon yours and Dr. Muhl's testing regarding the
24 fact that 75 percent of this would be covered by scar
25 tissue, do you have an opinion that just that design

1 buy the 1 millimeter pore size, let me ask you, in the
2 worldwide peer-reviewed literature since this concept
3 came out in the late '90s, early 2000s by you and the
4 group at Ethicon -- you and the group at Norderstedt
5 with Ethicon, have you ever seen anywhere in the
6 scientific literature anyone who has refuted or
7 disputed or who has been able to state that you were
8 incorrect with greater than 1 millimeter?

9 A I never got aware of data that are in
10 contradiction to this message. The term "large pore"
11 is better than small pores, I think there are numerous
12 citations in the literature. It's well accepted. And
13 even in the many records from Ethicon I reviewed, I saw
14 these terms of large pores is necessary. They are
15 adopted in these presentations in these documents. And
16 I've never seen a sentence where they say no, it's not.
17 And I've never seen, and you can believe me, if it's
18 wrong, science will lead to publications that will show
19 that you made a mistake. So I never saw a -- someone
20 who could prove by data or by looking with a microscope
21 to the tissue response that this 1 millimeter is not
22 right.

23 Q We're going to talk about the testing that
24 Dr. Muhl did and that he spoke to this jury about last
25 week. I'm going to talk about that in just a couple

1 alone would be unsafe in a woman's pelvis permanently?

2 A As I said, there is a structural problem of this
3 design because of these crossing filaments.

4 Q Even before we talk about putting any
5 stress on the product. Correct?

6 A Yes. Even before this. If you leave them off,
7 if you remove these filaments, the scar formation will
8 be less.

9 Q Let's talk a little bit.

10 Did you have an opportunity -- from your
11 review of all the documents and the deposition
12 testimony, did you have an opportunity to learn how it
13 is that Ethicon was trying to test pore size prior to
14 launching Prolift in 2005?

15 A Yes, I did.

16 Q Well, wait. Look over to the right of that
17 diagram.

18 Do you see that?

19 A Yes.

20 Q And it says pore size in millimeter
21 squared, and they list a variety of different pore
22 sizes.

23 2.3, these -- this listing, what's your
24 understanding as to what they were doing there?

25 A So obviously they are looking to some few cells,

1 and they are trying to measure the area, the total
2 area. That means the total number of white pixels in
3 this area. And this means that you have an area -- and
4 if you made a -- if you assume that it is a square, you
5 can calculate the root out of it, and then you may have
6 an estimate of the pore size.

7 But this is not correct, because everyone
8 can see that it is not a square. These are irregular
9 forms of it. So the measurement of the area, the
10 calculation of the area is one thing that has been
11 tried to find out what is the percentage of good pores
12 there. But it's not very precise.

13 Other ways has been that with a ruler, you
14 just took out some of these pores and tried to measure
15 the distance.

16 Q I need to orient the jury.

17 You said that one way that Ethicon was
18 looking at pore size prior to launching Prolift was
19 they were just trying to calculate a square area.

20 Correct?

21 A Yes.

22 Q A second way that Ethicon was looking at
23 measuring pores prior to March 2005 was how?

24 A That was done just by -- with a ruler, where you
25 measure the distance here in between, and then maybe

1 you get a figure of 2 millimeters or so. But this is
2 not represented to reflect the percentage of good pores
3 in such a mesh structure. It just gives one diameter
4 in one pore, so this is not sufficient to get any
5 information how good a mesh will perform in the body.

6 Q Does the pore have to be 1 millimeter in
7 diameter?

8 A To every side. It has to be at least, at least
9 1 millimeter to all sides.

10 Q So is the manner in which to properly test
11 this to see how many 1 millimeter diameter spheres will
12 fit into any of these holes?

13 A That is eventually the procedure that Prof. Muhl
14 put to an automatic analysis, yes.

15 Q Can I see the next slide, please?

16 In discussing this pore size specification,
17 it seems like a lot of data up there. But is this
18 concept of pore size critical to the Gynemesh PS and
19 your opinions?

20 MR. GAGE: Your Honor, same objection to
21 the showing --

22 THE COURT: Your objection is preserved but
23 overruled.

24 BY MR. ANDERSON:

25 Q Before we get into this data, is pore size

1 critical in your opinion in order to determine whether
2 or not this would safely be implanted in a woman's
3 body?

4 A Yes, yes.

5 Q So we were talking about some information
6 that you had with regard to how Ethicon said that they
7 were measuring their pores. An e-mail from Scott
8 Ciarrocca to Dan Burkley.

9 Did you understand Dan Burkley to be the
10 person at Ethicon who was in charge of measuring pores
11 on Gynemesh PS?

12 A Yes, I did.

13 Q "Susan Lin informs me that you have" --
14 this is Ciarrocca to Burkley.

15 "Susan Lin informs me that you have a
16 visual technical manual for measuring mesh pore size.
17 Is this a documented standard and is it used in
18 production or development, or is it just employed to
19 compare our mesh to competitors?"

20 Did I read that read?

21 A Yes.

22 Q Let's see what Dan's response is to
23 Ciarrocca.

24 "That is not exactly correct. I developed
25 a procedure for measuring porosity many years ago when

1 one of the mesh teams at the time asked me if I could
2 measure porosity. I asked them, what do you mean by
3 porosity? I didn't get a response from any of the nine
4 team members, so I defined my interpretation of
5 porosity and how I could measure it, which turned into"
6 this number over here. "That represents the amount of
7 open space in mesh, which I define as a percentage of
8 porosity. It can be measured a number of different
9 ways. This procedure won't be appropriate for all
10 meshes. There is no written test method or procedure
11 for pore size."

12 Was that your understanding, that before
13 Gynemesh PS was launched, that Ethicon did not have a
14 written standard or test method for looking at pore
15 size?

16 A Yes.

17 Q "Pore size could be measured, but I've
18 asked members of mesh teams what they want when they
19 have a mesh that has different sizes because of
20 construction, such as Prolene Soft Mesh."

21 And that's what we just were looking at
22 with the jury, right, the pores are all different
23 sizes. Correct?

24 A Yes. This is the third possibility to get a
25 figure about porosity.

1 Q Okay. Just one second.
 2 "Many don't know and a few ask for all the
 3 different pores in the construction, which is a
 4 challenge.
 5 "All examinations have been done for
 6 research purposes for competitive assessment. None
 7 have been performed to compare to a specification, nor,
 8 to my knowledge, has a specification been created."
 9 And this was being sent in 2009. Correct?
 10 A Yeah.
 11 Q So was it -- is it your opinion that prior
 12 to Prolift being launched in March of 2005, that
 13 Ethicon did not have a specification for measuring pore
 14 size?
 15 A Yes, that is correct. This procedure that is
 16 proposed there is just the relation between white
 17 pixels and black pixels and is not focused on the pore
 18 size. It is not able to do so.
 19 Q This method just tells you the percentage
 20 of open space. Correct?
 21 A Yes.
 22 Q And then the other method that you saw that
 23 some people at Ethicon were using was just a line to go
 24 across the pore to say, oh, this is how long I think it
 25 is?

3468

1 A Yep.
 2 Q And the other way was to say let's see what
 3 the area is in the square area in these things that are
 4 not square. Correct?
 5 A The letter is what we would call today the
 6 textile porosity, but it's not accurate as well.
 7 Q Would any of these three methods that
 8 Ethicon seemed to be using prior to March 2005 tell you
 9 anything about how many 1 millimeter pores you have in
 10 all directions?
 11 A No, none.
 12 Q Would any of these test methods tell you
 13 how many greater than 1 millimeter pores are
 14 distributed throughout the mesh?
 15 A No.
 16 Q Would any of these test methods tell
 17 Ethicon what would happen in a woman's pelvic tissue
 18 for the rest of her life with regard to these pores
 19 with bars between them?
 20 A These techniques or these procedures are not
 21 sufficient to predict this risk.
 22 Q So prior to Prolift being launched in March
 23 of 2005, from the documents you've reviewed and these
 24 different test methods that you've looked at, do you
 25 have an opinion as to whether they had any idea whether

1 they had greater than 1 millimeter pore size in
 2 Gynemesh PS, and if so, over how much of the product?
 3 Did they know?
 4 A They knew that it was important, but they didn't
 5 know what happens in this textile structure in this
 6 place.
 7 Q Because they didn't measure it. Correct?
 8 A They didn't know to measure it.
 9 Q Next slide, please.
 10 Another e-mail, this is in June of 2006, a
 11 year after Prolift is launched, from Bob Rousseau to
 12 Scott Ciarrocca, "Pore size in microns was not measured
 13 during the development of Prolene Soft Mesh. The total
 14 percent area that is open was measured and is
 15 considered an accurate method. Since the product
 16 construction results in irregular pore geometries and
 17 sizes, it is not accurate to report a distinct pore
 18 size."
 19 Did I read that correctly?
 20 A Yes.
 21 Q So if someone comes before this jury and
 22 says we meet the 1 millimeter in all directions pore
 23 size requirement because we have 2.5-millimeter pores,
 24 if someone gets in front of this jury and says we have
 25 2.5-millimeters pores, what you would say?

3470

1 A Anyone who is coming here and saying we have a
 2 mesh with one figure of pore size, that is not true,
 3 because everyone will see or can see that if you look
 4 to this image of the pores, that you always have a mix.
 5 You have many variation of these pores.
 6 So the critical information is, what is the
 7 area of the good pores in relation to the mesh area?
 8 And, therefore, it is necessary to measure exactly the
 9 pore -- every pore.
 10 Q And based upon the amount -- based upon the
 11 information that you have and the testing that was
 12 done, what percentage of good pores were there in
 13 Gynemesh PS even before strain was placed?
 14 A It was around 7 -- 25 percent.
 15 Q So 75 percent would be bad pores?
 16 A Yes.
 17 Q 75 percent would cause fibrotic bridging?
 18 A Will cause -- will be bridged by scar tissue,
 19 yes.
 20 Q Scar plate?
 21 A Scar plate, shrinkage.
 22 Q Shrinkage?
 23 A And so --
 24 Q So if someone has a Gynemesh PS implant in
 25 them in the form of a Prolift and they have retracted

1 arms of the mesh, is that explained by improper pore
 2 size, fibrotic bridging, scar plate and shrinkage?
 3 A Yes.
 4 Q If someone has bunching of the mesh that is
 5 causing pain and other problems, and they've been
 6 implanted with a Gynemesh PS Prolift, is this an
 7 explanation as to why that would occur?
 8 MR. GAGE: Objection. I don't believe
 9 there's a sufficient foundation, Your Honor.
 10 THE COURT: The objection is overruled.
 11 I'll allow him to answer from his view as an engineer.
 12 Proceed.
 13 BY MR. ANDERSON:
 14 Q You've seen in the literature and other
 15 places that sometimes it's called bunching, sometimes
 16 it's called contraction, sometimes it's called
 17 shrinkage. Correct?
 18 A Yes.
 19 Q So if someone had what was described as
 20 bunching of the mesh that's been implanted with
 21 Prolift, would that be explained by improper pore size,
 22 fibrotic bridging, scar plates and mesh shrinkage?
 23 A Yes. All these problems that are related to
 24 excessive scar formation are explained by this
 25 structural disadvantage.

3472

1 Q Thank you. Slide 15, please.
 2 Is this what we were just discussing, that
 3 effective porosity, after you account for the pores
 4 that will have 1 millimeter in all directions based
 5 upon Dr. Muhl's report, that this will only have
 6 effective or open pores of 26 percent?
 7 A Yes. Effective porosity, that is the area of the
 8 good pores, to say it simple.
 9 Q Dr. Muhl was asked by defense counsel last
 10 week why it was -- well, strike that.
 11 Defense counsel asked Dr. Muhl a number of
 12 questions last week that he couldn't answer because he
 13 said I'm not a medical doctor, you'll have to ask Dr.
 14 Klinge. Okay?
 15 A Thank you.
 16 Q So I want to ask you some of those
 17 questions today. Okay?
 18 A Yes.
 19 Q I don't think it bears repeating, but
 20 obviously the reason that you told him to have the
 21 machine automated to look at Gynemesh PS and to find
 22 the 1 millimeter pore areas is because of everything
 23 that we've been discussing this morning regarding the
 24 critical pore size of 1 millimeter. Correct?
 25 A Yes. The advantage of his procedure is that it

1 can be done automatically. It is a lot of work to do
 2 it by hand, to look whether these pores are big enough,
 3 so he proposed an algorithm that a machine can make an
 4 analysis of all these pores automatically within some
 5 minutes.
 6 Q But even though it may be a lot of work,
 7 prior to March of 2005, Ethicon, Dan Burkley and these
 8 others, could have measured the pores to see how many
 9 of them were greater than 1 millimeter in all
 10 directions, couldn't they?
 11 A They could.
 12 Q There was software available as well that
 13 could have done that for them. Correct?
 14 A They could have done it. There is no real
 15 invention in this measurements of Muhl.
 16 Q What you and Prof. Muhl did in that work
 17 between 2005 to 2007 was just an automated way to count
 18 the pores --
 19 A Yes.
 20 Q -- and see how many were larger than
 21 1 millimeter. Right?
 22 A They applied what we otherwise would have to do
 23 by hand, that this was done just by a computer program.
 24 Q But in the e-mail from Dan Burkley when he
 25 said some of the team members have asked me to measure

3474

1 all the pores but that's a challenge, just because it
 2 was a challenge didn't mean he couldn't have done it.
 3 Correct?
 4 A Yeah. But if he -- when he ask what may be the
 5 reason, what do you think what is important with pores,
 6 and none could answer this, I think that is an
 7 explanation why they didn't go on further.
 8 Q Let's look at the next slide, please.
 9 You've seen this from Dr. Muhl's report as
 10 well?
 11 A Yes.
 12 Q Explain at the top, this is Prolift arm,
 13 and we have different amounts of tension.
 14 Can you explain to the jury why you chose
 15 these four different amounts of tension, from zero to
 16 1,000?
 17 A When we decided to apply some tension to these
 18 textile structures, we have to define what range should
 19 be applied to these structures. And one critical point
 20 was that we knew from our previous work that beyond 20
 21 newton, that means 2 kilogram per centimeter, that the
 22 tissue is going to rupture. So we are convinced that
 23 we don't need any textile structure that is stronger
 24 than the neighboring tissues. So the upper point was
 25 20 newton.

1 So the next point was that we wanted to
 2 have a certain elongation of the mesh. And we have,
 3 according to the studies in the literature, that we
 4 should have been or there should have been expected an
 5 elongation, if it's placed in the tissue, by about
 6 20 percent. This should be comfortable, not to hinder
 7 the mobility of the tissue very much. But it's a rough
 8 estimate about it. But we wanted to have an elongation
 9 of 20 percent. And we have seen that Ethicon, they
 10 expected that during the implantation, there was
 11 applied some sort of strain to this material to the
 12 arms. And we wanted to stay far below.

13 And, therefore, the reason was, and we
 14 wanted to have very simple numbers. And, therefore, we
 15 decided to place a load of 1 kilogram, 500 gram, 250
 16 gram and to look what happens there to the textile
 17 structure to see whether the one is better than the
 18 other.

19 Q So with the first slide that -- the slide
 20 before this that we saw, that's where the machine has
 21 no force on the Gynemesh PS and it's just calculating
 22 how many pores there are that are greater than
 23 1 millimeter in all directions. Correct?

24 A That is correct.

25 Q And that was only pores -- I think

1 mechanical stress should be done, first of all, in a
 2 uniaxial way.

3 Q Is this something that Ethicon could have
 4 done before March of 2005 with the Gynemesh PS, and
 5 that is to look at what the pores would look like under
 6 some minimal strain?

7 A To put strain or a mechanical load to a mesh, it
 8 is nothing that couldn't have been done.

9 Q In your opinion, should Ethicon have looked
 10 at the effective porosity, the amount of open pores
 11 after 1 millimeter, and should Ethicon have looked at
 12 those pores after some minimal amount of strain before
 13 selling this to be permanently implanted into a woman's
 14 body?

15 A Yes. Always when you intend to use a mesh in an
 16 area where you cannot rule out that it is really
 17 tension free, that there occurs some mechanical load,
 18 you have to look what happens to the pores in case the
 19 stress will appear.

20 Q Was Ethicon aware of a study that you and
 21 Prof. Muhl had done in 2007?

22 Next slide, please.

23 MR. GAGE: Same objection, Your Honor, just
 24 preserve the record.

25 BY MR. ANDERSON:

3476

3478

1 26 percent?

2 A 26 percent of the pores.

3 Q Then when you applied these various forces,
 4 Prof. -- Dr. Muhl did this in his machine, what
 5 happened when 1.65 pounds of force was placed on arm 3?

6 A If you apply a mechanical load of 500 gram or
 7 1.6 pounds, then the good pores disappeared completely.
 8 So that means when you place this mesh in an area where
 9 this load is applied, at some time, for however, in
 10 this moment, the good pores will disappear, and then a
 11 complete fibrotic bridging of the entire mesh area will
 12 occur.

13 Q And Dr. Muhl was asked by defense counsel,
 14 well, why did you use uniaxial testing, pulling it like
 15 this?

16 Can you explain to the jury why this was
 17 part of this test?

18 A Yeah. Because multiaxial is really not possible.
 19 But this was not intended to make a simulation of the
 20 pelvic floor and of the many different forces. We know
 21 that the arms are stressed in a uniaxial way, because
 22 it is stretched only from one side. We know that
 23 ligaments mainly are stressed in a uniaxial way. So,
 24 therefore, we are convinced that to get an impression
 25 about the stability of the meshes to withstand some

1 Q Before we get to that, did you have an
 2 opportunity to look at the Ethicon documents to see
 3 what they estimated the forces to be that would be
 4 placed on the arms?

5 A Yes, yes, I've seen it.

6 Q And one of them says 5 pounds of force?

7 A Yes.

8 Q And the other area was 12 pounds of force?

9 A Yes.

10 Q And what were the pounds of force that we
 11 just said at 1.65 pounds, what happened to the mesh?

12 A 1 -- yeah. At a load of 1.6 pounds, the good
 13 pores disappeared completely already. So it's far
 14 below these values.

15 Q Next slide, please.

16 And is that what's represented here in the
 17 Muhl finding, that over here under 3.3 pounds, it turns
 18 into that configuration?

19 A Yes. And this image clearly shows that the
 20 elongation is done by deformation of the pores.

21 Q And at even half that, which was 500, at
 22 even half of that, 1.65, there was zero effective
 23 porosity. Correct?

24 A Yep.

25 Q Nowhere for the body to allow fat tissue

1 ingrowth to make it flexible?

2 A No.

3 Q Only places where scarring would come into

4 the pores and encapsulate this mesh in rigid scar

5 plate. Correct?

6 A That is correct.

7 Q Leading to shrinkage?

8 A Shrinkage.

9 Q Leading to patient complications?

10 A Yes.

11 Q Next slide, please.

12 I was asking you before if out of the

13 documents you reviewed, whether or not Ethicon was

14 aware of this testing and this article that you and

15 Muhl had published in 2007. I believe the jury saw

16 this one the other day.

17 "Interesting article that may give us some

18 guidance on what we measure on the mesh

19 characterization. Aachen has a very sophisticated

20 setup but does address the question of what should be

21 measured and what is the relevance of the measurement."

22 Have you seen that document?

23 A Yes, I've seen it.

24 Q The next document please.

25 Yeah, it's right there.

1 "Hi, Marty, I just got my hands on this

2 article on porosity and thought you might be

3 interested."

4 You've seen these documents?

5 A Yes.

6 Q Next one, please.

7 And you've seen this by -- this e-mail from

8 Joerg Holste.

9 And who was Joerg Holste?

10 A Joerg Holste was, for 30 years, one of the

11 principal investigators at the R&D department for

12 Ethicon in Norderstedt.

13 Q Did you work closely with him over the

14 years?

15 A For many years we did.

16 Q And do you understand Juergen Trzewik, who

17 he is sending this e-mail to, is the top biomechanical

18 engineer at Ethicon?

19 A At that time, yes.

20 Q And he forwarded it to him, your article.

21 Correct?

22 A Yes.

23 Q Go to slide 22.

24 Did you see in the Ethicon documents that

25 you reviewed, Dr. Klinge, that they were aware of the

1 importance of looking at pore size after stretch was

2 placed on their meshes?

3 A Yes.

4 Q And how is this significant to you, this

5 number 4 that we have called out?

6 A In this document, it is clearly that they

7 recognized and they accepted that the requirements for

8 the good mesh, that this came out of the new projects

9 which were initiated to find a better material, and the

10 requirement was defined as pore size of more than

11 1 millimeter under stretch. And that means that

12 without stretch, you should estimate -- or you should

13 go to a pore size of more than 3 millimeters. That has

14 been defined as optimum requirement for a better mesh.

15 Q So no matter what your pore size is that

16 you start out with, if you're going to put sufficient

17 strain on it, no matter what that strain is, you need

18 pore sizes greater than 1 millimeter after that.

19 Correct?

20 A Yes.

21 Q And you need pore sizes greater than

22 1 millimeter to keep this scar tissue from growing in.

23 Correct?

24 A Yes. That is their definition of good mesh, and

25 it is quite clear that the Prolift will fail such a

1 test.

2 Q So they're looking at this in 2008.

3 Had they done it in 2005, Prolift would

4 have failed?

5 A They would have exchanged it by another.

6 Q Next slide, please.

7 There is some question as to whether or not

8 Ethicon was aware of the concept of effective porosity.

9 I want to show you this document from August 2008.

10 What do you see there on the left?

11 A On the left side, you see almost exactly that is

12 the test I did with Prof. Muhl. You apply the

13 mechanical load to a textile structures. So this is

14 done -- this is in total agreement to our understanding

15 what is important, that you need these pores, that you

16 have to guarantee that even under mechanical load you

17 have these good pores. And they did it.

18 Q They did it three years after the product

19 was launched?

20 A Yes. But this means that there is no

21 contradiction in the content of this, what we have

22 studied for 20 years. So these are not data that are

23 showing that we are -- that we are wrong in this. So

24 it is very clear, this concept still is valuable and it

25 is still accepted in Ethicon as well.

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1 Q Do you have an opinion as to whether or not
2 Ethicon should have done this for Gynemesh PS prior to
3 putting it on the market in 2005?
4 A Definitely. It was quite clear that you need
5 large pores at that time point. And, therefore, you
6 have to measure it.
7 Q You mentioned before when talking about the
8 various forces and why you chose the forces in the
9 uniaxial fashion, first of all, that would be force in
10 a uniaxial fashion on one of Ethicon's meshes.
11 Correct?
12 A Yes.
13 Q And when you said you chose something less
14 than 2 milligrams of force because you said most
15 tissues will rupture above 2 kilograms of force.
16 Correct?
17 A That is correct.
18 Q You guys used half of that, which is what's
19 represented in the middle picture up there. Correct?
20 MR. GAGE: Objection, Your Honor. Leading
21 questions.
22 MR. ANDERSON: I'll withdraw it.
23 BY MR. ANDERSON:
24 Q Is that in the middle half of the top
25 amount of what you used in the other testing?

3484

1 A Yes.
2 Q And they used double -- strike that.
3 Did they use double that amount in the
4 bottom drawing?
5 A Yes. But I think it will depend from the
6 indication which load has to be applied there. So I
7 think we are in a good range there.
8 Q Next slide, please.
9 Show the jury an e-mail that they saw a
10 couple weeks ago, maybe even on Friday. 11/23/05.
11 This is an Axel Arnaud e-mail regarding information
12 that was being given by a Prolift surgeon, Dr.
13 Eberhard.
14 And this is eight months after Prolift was
15 launched. Correct?
16 A Yes, that is correct.
17 Q Number 5, he, Dr. Eberhard, is reporting to
18 Axel Arnaud, "He believes that after retrieval of the
19 cannula, the straps take a rope-like shape which is not
20 optimal in his opinion. He has observed that some
21 patients have discomfort as they can feel the straps
22 with Prolift." It says, "The Perigee implants lie
23 flat."
24 Why is this significant to your opinions,
25 if at all, Doctor?

1 A It demonstrates that there is a concern that the
2 arms will not -- even at that time point, will not
3 preserve its structure when it's placed into the human
4 body.
5 Q And if we have curling and roping and pore
6 deformation of -- strike that.
7 If there is curling and roping and pore
8 deformation in the arms going through a woman's groin
9 and through her buttocks, do you have an opinion as to
10 what will occur after she goes home from surgery and
11 for the rest of her life with this mesh in her?
12 A If you have these curling and shrinkage, there is
13 no chance for any place in the arms to be filled by fat
14 tissue, but this will incorporate it into scar tissue
15 completely.
16 Q Is that dangerous for the patient?
17 A That is a safe concern -- a safety concern.
18 Q Let's see the next slide, please.
19 Dr. Klinge, you've seen the implantation
20 videos, the training videos by Ethicon. Correct?
21 A Yes, I have seen it.
22 Q Can you play this short clip?
23 MR. GAGE: Objection, Your Honor. Can we
24 approach?
25 - - -

3486

1 (The following occurred at sidebar:)
2 MR. GAGE: I'm assuming they're going to
3 show the arms and show the roping and curling. This is
4 exactly the testimony that we went through with Dr.
5 Weber, and it's cumulative between the experts, and I
6 would ask that it not be done.
7 MR. ANDERSON: This is the top biomaterial
8 scientist in the world that worked with them. He has
9 now gone through and described that Muhl has --
10 THE COURT: I'm going to deal with it
11 briefly.
12 How much longer are you going to be?
13 MR. ANDERSON: Five minutes, ten minutes.
14 THE COURT: Because their lunch is here.
15 So do the rest and then we'll break.
16 MR. ANDERSON: Thanks.
17 - - -
18 (The sidebar ended.)
19 - - -
20 BY MR. ANDERSON:
21 Q I'm sorry to have to show this again. And
22 we're just going to show a brief clip to demonstrate
23 what we've been talking about here. Okay?
24 A Yep.
25 Q Can you show that, please?

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1 Do you see the arms over on the right
 2 coming out of the woman's groin, Dr. Klinge?
 3 A Yes.
 4 Q And do you see the ones on the left coming
 5 out?
 6 A Yes.
 7 Q Explain what you are seeing here in terms
 8 of what we've been discussing, curling and roping and
 9 these problems that could occur as a result.
 10 A Yeah. You see in this video that the arms get
 11 curled, that they are -- the appearance is a rope
 12 there.
 13 Q And as that rope comes through the tissue,
 14 would you expect that these polypropylene arms here
 15 will just magically spring back out flat like this?
 16 MR. GAGE: Objection, leading.
 17 BY MR. ANDERSON:
 18 Q Would you expect from this diagram right
 19 here as those arms are laying in the woman's groin and
 20 curled, would you expect those to pop back into shape?
 21 A No, no, no. Certainly not.
 22 Q Explain that to the jury, please.
 23 A Certainly not. The power of these small 5-0
 24 polypropylene fibers to spring back into original form
 25 is quite low. So if you place this in this rope form

3488

1 in the tissue where all the tissue around is going to
 2 this one, there is no sufficient force to say, okay, I
 3 push the cells back again and then I'm coming to a
 4 plane -- to a plane shape again. So it is not
 5 reasonable, for my experience not.
 6 If you believe in this, you should try to
 7 test it and to study it. But I have serious doubts
 8 that it will not be possible if you have a rope mesh,
 9 then it spring off again. That would mean in the field
 10 of abdominal wall hernia, if you place a hernia mesh
 11 there in a -- yeah, a wrinkled form, that the surgeon
 12 should not concern any longer because it's springing up
 13 again and it's lying flat. No, it's not like this. So
 14 if it is placed in this configuration in tissue, it
 15 will stay there. That is my opinion to this.
 16 Q From all the documents that you reviewed,
 17 did you see anywhere where Ethicon tested what would
 18 occur due to this roping prior to launching the Prolift
 19 in March 2005 for this product to be permanently
 20 implanted into woman? Did you see that anywhere?
 21 A I didn't -- no, no.
 22 Q In your opinion, should Ethicon have tested
 23 to see what would happen to the arms after it was
 24 curled and roped like this and going all the way
 25 through a woman's groin and through her buttocks?

1 Should they have tested that?
 2 MR. GAGE: Objection, leading, Your Honor.
 3 THE COURT: The objection is overruled.
 4 You can answer.
 5 MR. ANDERSON: Thank you.
 6 THE WITNESS: If the arms are looking like
 7 this, it is necessary to look what happens in the
 8 tissue with these arms. Because -- or you should
 9 develop another textile structure so that the arms look
 10 different than this one. But you have to do something.
 11 BY MR. ANDERSON:
 12 Q Do you have an opinion, Dr. Klinge, if what
 13 the jury is seeing with this roping in the arms is
 14 similar to the roping that you and Dr. Muhl saw when
 15 you did your testing on the mesh?
 16 A Yes. It's quite similar appearance. And you
 17 don't need even a microscope. Everyone can -- if you
 18 take the arms and put some mechanical strain to it, you
 19 will see this deformation of the pores, so --
 20 Q At the strain of either 5 pounds of force
 21 or 12 pounds of force or some greater force as was
 22 stated by Ethicon?
 23 A This happens by comparatively low forces. And
 24 this has to be studied in relation to the indication
 25 where you place it.

3490

1 Q Last slide, please. Can you highlight that
 2 part?
 3 You've seen this document. Correct?
 4 A Yes.
 5 Q "Jennifer, I'll just weigh in on this
 6 specifically designed synthetic mesh. This mesh was
 7 not specifically designed for Prolift application. We
 8 pulled it out of our existing bag of tricks. So a
 9 statement that it's specifically designed is
 10 unsupportable from a design history standpoint."
 11 Do you see that?
 12 A Yes.
 13 Q Dr. Klinge, do you have an opinion as to
 14 whether or not it is sufficient to take a hernia mesh
 15 that's been adapted for hernia use and to sell it for
 16 pelvic floor use without proper testing?
 17 A Yes.
 18 Q What is that opinion?
 19 A I think that it is not sufficient. And I thought
 20 we made it clear by all our experiments that you have
 21 to make -- find a specific design for the specific
 22 indication in a specific area, and, therefore, you have
 23 to define the requirements specifically for this
 24 purpose. And it is not suitable or adequate to just
 25 put from one area in the body a textile and place it in

1 another.
2 Q Three more questions.
3 Based upon all of your work for 20 years,
4 your work in the industry, all of your publications and
5 your career in looking at surgical issues related to
6 surgical meshes, biomaterials science, tissue response,
7 histopathology and your work in this field for 20
8 years, as well as your review of all of the materials
9 you saw in this case related to the depositions and the
10 internal documents by Ethicon, do you have an opinion
11 as to whether or not Gynemesh PS in the Prolift is a
12 defective product?
13 A Yes.
14 Q And what is that?
15 A It was a defective product.
16 Q Do you have an opinion as to whether or not
17 the Prolift/Gynemesh PS was unreasonably dangerous when
18 it was sold in March of 2005 to be permanently
19 implanted into women?
20 A Yes.
21 Q And what's that opinion?
22 A It was dangerous.
23 Q Do you have an opinion as to whether or not
24 Ethicon should have ever sold Prolift with this
25 Gynemesh PS in it in March of 2005?

3492

1 A Yes.
2 Q And what's that opinion?
3 A They should never have sold it.
4 MR. ANDERSON: No further questions at this
5 time, Your Honor.
6 THE COURT: Okay. We'll break for lunch.
7 We'll just take a half hour and we'll be back at 1:00.
8 - - -
9 (The jury leaves the courtroom.)
10 - - -
11 (A recess was taken from 12:28 p.m. to
12 1:12 p.m.)
13 - - -
14 THE COURT: You can be seated. Bring the
15 jury in. The witness can resume the stand.
16 - - -
17 (The jury enters the courtroom.)
18 - - -
19 THE COURT: You may proceed.
20 MR. GAGE: Thank you, Your Honor.
21 - - -
22 CROSS-EXAMINATION
23 - - -
24 BY MR. GAGE:
25 Q Good afternoon, Dr. Klinge. How are you?

1 A Good afternoon.
2 Q Good. My name is William Gage. I'm a
3 lawyer and I represent Ethicon. And you and I have not
4 had the pleasure to meet, so welcome to the United
5 States.
6 A Thank you very much. It's a pleasure.
7 Q Now, sir, you've been paid about \$100,000
8 for this case. Correct?
9 A Yes.
10 Q And when I did the conversion this morning,
11 I went to the website and said how much is that equal
12 to in Euros, and I think it's about 1.36 Euros.
13 Does that sound about right to you?
14 A Yes. It changes.
15 Q It changes daily, but if we had 100,000 --
16 if you got 100,000 bucks, and that's basically for the
17 work that you did in 2012. Right? I mean, most of
18 your work was in the year 2012 on this case?
19 A From my feeling, there has been a lot of work
20 this year as well, but --
21 Q Let's stick mostly --
22 A It's for the entire time period here.
23 Q Let's stick with 2012.
24 If we got an exchange rate of about 1.36 or
25 something like that, 100,000 US dollars is about

3494

1 136,000 Euros. Correct?
2 A Yes.
3 Q And you were kind enough to tell us at your
4 deposition that you're actually employed by the
5 University of Aachen; is that right?
6 A That is right.
7 Q I think you told us that -- you were kind
8 enough to tell us at your deposition that your salary
9 there is about 80,000 Euros a year?
10 A The salary is maybe more to 90,000 Euros a year.
11 And the income of my family there, in 2010, for techs,
12 was in about 160,000 Euros.
13 Q So the work for the University is somewhere
14 around 90,000 Euros?
15 A Yes.
16 Q So the money that you would have gotten
17 paid on this case would be one-and-a-third what you
18 would get paid in a given year for your salary at the
19 university. Right?
20 A I think you calculate it correctly.
21 Q Now, sir, just to make sure we got
22 everything clear, you've never treated Ms. Gross.
23 Correct?
24 A That is correct.
25 Q You never examined her?

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1 A That is correct.
 2 Q And you've certainly not rendered any
 3 medical diagnosis specific to Ms. Gross. Correct?
 4 A That is correct.
 5 Q And you've not examined -- you know, you
 6 testified and you've talked about explants of mesh that
 7 you've examined. Correct?
 8 A Yes.
 9 Q And that's where mesh is taken out of
 10 somebody's body and you look at it, for example, under
 11 a microscope. Correct?
 12 A That is correct.
 13 Q And you've not examined any mesh explanted
 14 from Ms. Gross. Correct?
 15 A That is correct.
 16 Q And you have not examined any mesh that may
 17 still be inside Ms. Gross. Correct?
 18 A That is correct.
 19 Q Now, sir, in your expert report, you were
 20 kind enough to tell us that you've never performed
 21 surgery for repair of stress urinary incontinence.
 22 Correct?
 23 A That is correct.
 24 Q That's surgery in the pelvic floor, in the
 25 vagina. Correct?

3496

1 A You can say so.
 2 Q And you've never performed surgery for the
 3 repair of pelvic organ prolapse. Correct?
 4 A That is correct.
 5 Q And that means you've never performed, for
 6 example, a native tissue repair, a colporrhaphy.
 7 Correct?
 8 A That is correct.
 9 Q And you certainly never performed a pelvic
 10 organ prolapse repair using a mesh. Correct?
 11 A That is correct.
 12 Q And obviously you've never used a Prolift.
 13 Correct?
 14 A That is correct.
 15 Q You've never used Gynemesh PS for a pelvic
 16 floor repair of any kind. Correct?
 17 A That is correct.
 18 Q And you've never placed a mesh with
 19 trocars. Correct?
 20 A That is correct.
 21 Q And you've never placed a mesh with
 22 cannulas. Correct?
 23 A That is correct.
 24 Q And you've never placed a mesh using the
 25 same tools as Prolift. Correct?

1 A That is correct.
 2 Q And, sir, you don't consider yourself an
 3 expert in the pelvic floor based upon the training you
 4 received in medical school. Correct?
 5 A I'm not an expert in pelvic floor surgery in
 6 regards to the surgical procedure.
 7 Q And I think you told us earlier, you're not
 8 an obstetrician or a gynecologist or a urologist or a
 9 urogynecologist. Correct?
 10 A Yes.
 11 Q You obviously completed no fellowships or
 12 residency or any other form of formal training in those
 13 fields. Correct?
 14 A That is correct.
 15 Q You've not studied the pelvic floor forces
 16 in a human. Correct?
 17 A That is correct.
 18 Q Sir, you stopped doing surgery. You told
 19 us that you had done hernia surgery, is that right,
 20 sir, for a period of time?
 21 A Can you say it again?
 22 Q Yes.
 23 You told us earlier that you did hernia
 24 surgery for a period of time. Correct?
 25 A That is correct.

3498

1 Q If I remember correctly, it's somewhere
 2 from around, what, the '90s up through about 2004,
 3 2005?
 4 A I started hernia surgery with the beginning of
 5 the residence. And this was in 1985. And stopped
 6 2006.
 7 Q 2006.
 8 A In December.
 9 Q So you hadn't been doing any hernia surgery
 10 since 2006. Correct?
 11 A Yeah.
 12 Q Now, sir, I want to talk to you a minute
 13 about polypropylene.
 14 Polypropylene is what Prolift and Gynemesh
 15 PS are made of. Correct?
 16 A That is correct.
 17 Q Sir, you talked -- at the beginning of your
 18 direct examination, you talked about, you made a
 19 reference to the phrase "the history of hernia
 20 surgery." And I believe you said that you had been
 21 asked to lecture on the history of hernia surgery.
 22 Do you recall mentioning that earlier this
 23 morning?
 24 A I represent the history of mesh research of 20
 25 years. So that was what I wanted to express.

1 Q And that's a subject, the history of hernia
2 surgery and use of meshes in hernia surgery is a
3 subject that you are familiar with?

4 A Yes.

5 Q Sir, I'm going to hand you an article, I'm
6 sure you've probably seen it before, "Historical
7 Development of Prosthetics in Hernia Surgery." And
8 this is published in the Surgical Clinics of North
9 America. Correct?

10 A That is correct.

11 Q Jamey, let's put up DLTB00647.

12 So we've got an article here, groin hernia
13 surgery. And, Jamey, if you go down to the very
14 bottom, you'll see that this is 1998. Correct, sir?

15 A That is correct.

16 Q And the title of it is, "The Historical
17 Development of Prosthetics in Hernia Surgery."

18 And, sir, when we talk about prosthetics,
19 we're talking about things like mesh. Correct?

20 A Yes.

21 Q Let's go over to .7, LT647.7. And let's
22 get this paragraph, "Polypropylene Mesh," kind of front
23 and center for us, Jamey. Thank you.

24 All right. So, sir, we see here --
25 actually, sir -- and, Jamey, you don't have to put this

3500

1 onto the screen, but, sir, you have got a copy of the
2 article there. And you can flip through it if you
3 wish.

4 But polypropylene mesh for use in the
5 hernia space was not the first time a mesh was used in
6 the hernia space. Correct?

7 A Please say it again?

8 Q Yes.

9 I mean, polypropylene mesh was not the
10 first type of mesh used by physicians to cure hernias
11 in surgical operations. Correct?

12 A That is correct.

13 Q In fact, doctors, really around the turn of
14 the 19th century, looked at a variety of different
15 substances and materials to repair hernias. Correct?

16 A That is correct.

17 Q They used things like stainless steel?

18 A Yes.

19 Q They tried to make meshes out of steel?

20 A Yes.

21 Q Fortisan?

22 A Steel is used in the sort of clinic as the
23 major -- as the best suture material they found. So
24 since 1944, they still used for this purpose sutures
25 made of stainless steel and still are thinking that

1 this is the best. So there are different opinions
2 about it and experiences, and it depends from the
3 purpose of where you want to use it.

4 Q I mean, there are a lot of different
5 opinions about what's being used. Right?

6 A Yeah.

7 Q Okay. So then we --

8 A It depends.

9 Q -- see polyvinyl sponge was once used or
10 considered as a material for use in the hernia space.
11 Right? You're familiar with that?

12 A Polyvinyl?

13 Q It's not on that particular page, sir. I'm
14 just telling you -- here. I said you could look back
15 in the article earlier. And you'll see that polyvinyl
16 sponge was once used as a potential material in the
17 repair of hernia surgeries.

18 Were you aware of that?

19 A I have to look through that. If you tell me
20 where I can find it?

21 Q Look at 647.3.

22 A 647.3. Yeah.

23 Q Do you see that heading "Polyvinyl Sponge"?

24 A I know this, yes.

25 Q If you flip over on the next page, sir, you

3502

1 see where nylon -- you're familiar with nylon.

2 Correct?

3 A I know it, yeah.

4 Q And nylon was another substance that
5 physicians and surgeons looked at as a possible way to
6 repair hernias in people. Correct?

7 A Yes.

8 Q And then we have another substance called
9 Silastic. Correct?

10 A Yes.

11 Q And that's a silicone-type product.
12 Correct?

13 A Yes.

14 Q And then Teflon, you see that on the next
15 page, that's another substance. You were aware of
16 that?

17 A Yes.

18 Q And then carbon fiber, that was another
19 substance that surgeons started looking at and saying,
20 you know, what can we use. That was another one.
21 You're aware of that. Correct?

22 A Yes.

23 Q And then we've got polyester, over on the
24 next page, that was another substance that surgeons
25 were looking for as a solution to the hernia space.

3503

3505

1 Correct?
 2 A Yes.
 3 Q And then we get to what we see on the page,
 4 after going through all that, on page 647.7, are you
 5 with me, sir?
 6 A 647.7?
 7 Q Yes. It's what's up on the screen.
 8 A Uh-huh.
 9 Q Do you see that?
 10 A Yes.
 11 Q It says, "Polypropylene mesh." And let's
 12 just do the first couple sentences there.
 13 All right. And what we see, "Usher," he
 14 was one of the early pioneering surgeons; is that
 15 correct, sir?
 16 A Yes.
 17 Q "Usher introduced a new polyethylene
 18 plastic mesh called Marlex 50 in a series of
 19 experimental and early clinical papers in 1958 and
 20 1959. This plastic mesh material had many obvious
 21 advantages over any type of metal mesh in use at the
 22 time."
 23 Do you see that?
 24 A Yes, I see it.
 25 Q And polyethylene is not exactly the same

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1 thing as polypropylene. Correct?
 2 A That is correct, definitely.
 3 Q Let's go over to the next page, LT647.8.
 4 And let's go down to the paragraph right here beginning
 5 "In 1962."
 6 Okay. So we see here, "In 1962, Usher
 7 reported a collective review of 541 cases of hernia
 8 repair with Marlex mesh."
 9 And that's the polyethylene that we just
 10 showed. Correct, sir?
 11 A It is correct that you read it. Whether it is
 12 correct, I don't know, because sometimes they change to
 13 polypropylene. And I didn't know when it was.
 14 Q That's exactly the point we're going to,
 15 sir.
 16 A Yeah.
 17 Q Look right here. Let's look right here.
 18 The -- let's do this whole paragraph right there,
 19 beginning with "The use of this."
 20 "The use of this new polyethylene mesh
 21 prosthesis grew rapidly after its introduction, and by
 22 1962, Adler" --
 23 Again, sir, another physician. Correct?
 24 A Uh-huh.
 25 Q -- "Adler found in a survey of general

1 surgeons throughout the United States that 20 percent
 2 were using it for complicated hernia repair. In 1963,
 3 an improved version of Marlex was introduced by Usher
 4 based on a new knitted mesh of polypropylene
 5 monofilament fiber, used initially as a suture
 6 material, and this remains the prosthesis in use today,
 7 marketed by CR Bard of Billerica, Massachusetts as
 8 Marlex mesh."
 9 Did I read that right?
 10 A Yes.
 11 Q So now it's 1963 and we've got a knitted
 12 mesh of polypropylene monofilament fibers. Correct?
 13 A That is correct.
 14 Q And if we talk about Prolift or we talk
 15 about Gynemesh PS, which is the mesh that goes into
 16 Prolift, we're talking about a polypropylene
 17 monofilament fiber. Correct?
 18 A Yes.
 19 Q Now, let's go down here. "In 1967."
 20 Right.
 21 So we see here, in -- the article is
 22 telling us that, "In 1967, Collier and Griswald
 23 described the routine use of polypropylene mesh in
 24 inguinal hernia repairs and reported 212 consecutive
 25 repairs without a failure and without an infection."

3506

1 Correct? Did I read that right?
 2 A You read it right.
 3 Q Now, let's go to 647.10. First few
 4 sentences of that paragraph, Jamey.
 5 "The expansion of laparoscopic surgery,"
 6 sir, that's where -- laparoscopic surgery in the hernia
 7 space is where you don't split somebody wide open in
 8 order to put a mesh in them. Right?
 9 A Right.
 10 Q You go in through the use of --
 11 A Trocars.
 12 Q -- trocars?
 13 And you push the mesh down the trocar or
 14 down the hole, and then you look inside and you're
 15 operating inside the abdomen, it's kind of a blind
 16 procedure, but you still are able to see. Right?
 17 A In some procedures, that is right.
 18 Q So I just wanted the jury to understand
 19 what laparoscopic surgery is. And I think we've
 20 described it.
 21 "The expansion of laparoscopic surgery
 22 showing an exponential growth as more and different
 23 procedures are being performed. Hernioplasty is now
 24 performed laparoscopically" --
 25 And hernioplasty, that's fixing the hernia

1 with mesh. Correct?
 2 A Hernioplasty?
 3 Q Yes.
 4 A Yes.
 5 Q -- "is now performed laparoscopically with
 6 the major benefits reportedly being minimal patient
 7 discomfort and prompt return to full activities and
 8 employment."
 9 Did I read that right?
 10 A You read it right.
 11 Q Now, let's go down a couple of paragraphs
 12 to the one beginning "Polypropylene."
 13 "Polypropylene mesh has had an enormous
 14 impact on surgery over the past 35 years, and countless
 15 patients have had their lives extended or improved by
 16 its application to numerous surgical problems. It is
 17 quite clearly and justifiably the most popular
 18 prosthetic mesh available today for surgical
 19 implantation."
 20 Did I read that correctly?
 21 A Yes, you read it correctly.
 22 Q Thank you. Jamey, you can take that down.
 23 A Am I allowed to give a comment on this or not?
 24 THE COURT: No. You have to just answer
 25 questions that are asked. And if your attorney wants

3508

1 to ask something in follow-up, he can do that.
 2 THE WITNESS: Thank you.
 3 BY MR. GAGE:
 4 Q Now, Doctor, I'm going to hand you an
 5 article, it's Defendant's Exhibit DLTB00170.
 6 Sir, are you familiar with this article?
 7 A No. I have to read it.
 8 Q Sir, I'm not going to quiz you heavily on
 9 this article, so if you've just familiarized yourself
 10 with it, can we move forward with some questions?
 11 A You see, it's difficult. You want to pose some
 12 questions whether you read it? I don't need to read it
 13 myself, because I can --
 14 Q That's fair enough.
 15 A If you say read it correctly, I can answer it.
 16 Q Perfect.
 17 A If you ask to the content, I have to read the
 18 entire text.
 19 Q That's fair enough, sir.
 20 We can see up here it's published in 1998.
 21 Correct?
 22 A That is correct.
 23 Q And it's the International Urogynecology
 24 Journal. Correct?
 25 A That is correct.

1 Q Sir, that's not a journal that you have
 2 ever subscribed to. Correct?
 3 A So far I know until now, not.
 4 Q I'm sorry, did you say no?
 5 A No.
 6 Q No. All right.
 7 Have you ever seen this article?
 8 A No.
 9 Q Anterior colporrhaphy, you understand what
 10 that is, don't you?
 11 A Yes.
 12 Q "Anterior colporrhaphy reinforced with
 13 Marlex mesh for the treatment of cystoceles."
 14 Do you know what a cystocele is, sir?
 15 A Yes.
 16 Q Jamey, let's get just the first couple of
 17 sentences of the abstract.
 18 "This study assesses the use of Marlex mesh
 19 in conjunction with anterior colporrhaphy for the
 20 correction of cystocele with or without urinary stress
 21 incontinence. A retrospective review was carried out,
 22 12 years of experience with 142 patients undergoing a
 23 modified anterior colporrhaphy reinforced with Marlex
 24 mesh."
 25 Did I read that right, sir?

3510

1 A Yes.
 2 Q So let's go back up to the top. Let's look
 3 at the date on that article.
 4 That's 1998. Correct?
 5 A That is correct.
 6 Q So if we've got 12 years experience with
 7 142 patients using Marlex, we're looking at, what, 1998
 8 minus 12 gets us back to the mid 1980s; is that right?
 9 A What is the question, 1998 minus 12 years?
 10 Q Yes. That gets us to what, 1986?
 11 A '86 that means.
 12 Q So we've got doctors implanting Marlex mesh
 13 for anterior colporrhaphy and for the treatment of
 14 cystoceles in the mid 1980s. Correct? According to
 15 this article?
 16 A According to this article, he studied some of
 17 these patients, but I didn't see the follow-up, how
 18 many, how he did it. So we have to go in the details
 19 to see how reliable these results were that he reported
 20 them. So I have to read it.
 21 Q Let's go to page 170.5. Let's go to the
 22 bottom paragraph where it says, "We believe."
 23 And we see, "We believe that the modified
 24 anterior colporrhaphy reinforced with Marlex mesh is a
 25 safe procedure which can be performed in a patient with

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1 symptomatic prolapse, even if it is their first
2 operation."

3 Did I read that correctly, sir?

4 A You read it correctly.

5 Q Sir, let's go back to the first page of
6 that article.

7 Go under "Materials and Methods." Just
8 highlight that first sentence there.

9 We actually -- we've got "January 1977 to
10 May 1992, 142 women underwent an extended anterior
11 colporrhaphy reinforced with Marlex mesh."

12 So it's actually, instead of '86, it
13 actually goes back to '97 -- I'm sorry, 1977. Right?

14 A You read it correctly, yeah.

15 Q Sir, I'm handing you another article. This
16 is Defendant's Exhibit DLTB00325.

17 Have you ever seen this article, sir?

18 A I don't recall.

19 Q All right. And if we go up there to the
20 top, the name of this journal is European Urology. And
21 its publication date is 2000, but we see that it was
22 submitted sometime in 1999. Correct?

23 A That is correct.

24 Q European Urology, that's not a -- that's
25 not a journal you subscribe to, is it, sir?

3512

1 A No.

2 Q And the title is "Tension-free vaginal mesh
3 repair for anterior vaginal wall prolapse." Correct?

4 A That is correct.

5 Q And let's scroll up a little bit, Jamey.

6 All right. So under "Objectives," "We
7 determined the efficacy of the use of a tension-free
8 Prolene mesh to correct a grade III anterior vaginal
9 wall prolapse recurrence." Correct?

10 A You read it correct.

11 Q And Prolene mesh was the precursor to
12 Prolene Soft Mesh. Correct?

13 A From the timeline --

14 Q Yes.

15 A -- it is I think not correct, because Prolene is
16 still sold, so it was a parallel development.

17 Q So I tell you what. Let me go to your
18 expert report and let's get the history straight before
19 we finish going through this article.

20 You told us in your expert report that
21 Ethicon's use of polypropylene as a suture material
22 dates back to the late 1960s. Right?

23 A May I have this expert report, sir, so I can take
24 a look through it?

25 Q Sir, just to make it easier for you, I'll

1 go ahead and flip to the page that I'm going to talk to
2 you about. Right there, page 9.

3 Sir, underneath your heading there in your
4 expert report, "Ethicon's development of polypropylene
5 mesh," you have there, "Ethicon's use of polypropylene
6 as a suture material dates back to the late 1960s."
7 Right?

8 A I see it.

9 Q When we talk about sutures, I'm from the
10 southern part of the United States and we call them
11 stitches.

12 A I can't comment on it.

13 Q But sutures, what we call stitches, are
14 polypropylene threads that are used throughout the body
15 to close wounds. Correct?

16 A If you say so, yeah.

17 Q Well, sir, I mean, I'm asking you.

18 That's what sutures are used for. Correct?

19 A Please again?

20 Q Yes.

21 Sutures are used -- they are polypropylene
22 threads or filaments that are used to close wounds.
23 Correct?

24 A Some wounds. Skin. So you would never suture
25 bowels with a polypropylene suture. You would never do

3514

1 so. So you have muscular damages you would treat,
2 maybe some skin, but you will never -- some soft
3 tissue --

4 Q Right.

5 A -- you will not use it for this.

6 Q And that's not -- I'm not trying to suggest
7 that it's used --

8 A I think --

9 Q -- in every single place. That's not what
10 I'm suggesting, sir.

11 I'm saying just simply that polypropylene
12 has been used as a suture material in certain places in
13 the body going back at least to the 1960s. Correct?

14 A No doubt about it.

15 Q And Prolene sutures, I'm reading now from
16 your expert report, Prolene sutures were developed into
17 a flat hernia mesh in 1975.

18 A Yep.

19 Q And they called that Prolene mesh?

20 A Yep.

21 Q Right? I mean, I'm just reading this right
22 out of your report; is that correct?

23 A Yeah.

24 Q So then Ethicon then developed -- and this
25 is on the next page of your report, Ethicon then

1 developed Prolene Soft Mesh, which got launched in the
2 year 2000. Right?

3 A Yes.

4 Q Okay. And then in 2002, Ethicon sold
5 Prolene Soft Mesh as Gynemesh PS. Right?

6 A Yeah.

7 Q And then it was in '05 when Ethicon used
8 the Gynemesh PS to go into the Prolift. Correct?

9 A That's correct.

10 Q So when we talk about Prolene mesh, and we
11 talk about an article in 2000, right, we're talking
12 about the Prolene mesh that Ethicon developed into a
13 flat hernia mesh in 1975. Right?

14 A Please again?

15 Q Yes.

16 We got an article here, 2000. Correct?

17 A Yes.

18 Q And this Prolene mesh right here, this is
19 not Gynemesh PS, is it?

20 A Obviously not.

21 Q Obviously not, because Gynemesh PS doesn't
22 come out until 2002. Correct?

23 A Yes.

24 Q So this is what has sometimes been referred
25 to as the heavier weight --

3516

1 A Yes.

2 Q -- Prolene mesh. Correct?

3 A Yes.

4 Q And the pores on the Prolene mesh are a lot
5 smaller than the pores on the Gynemesh PS. Correct?

6 A Yes.

7 Q A good bit smaller. Correct?

8 A Yes.

9 Q And if we put them under your effective
10 porosity testing, they would very likely fail the
11 effective porosity testing. Correct?

12 A Correct.

13 Q Okay. All right. So let's get reoriented.
14 Let's go back up to the top of the article. I just
15 want to make sure we've got everything squared away.

16 European Urology, 2000, "Tension-free
17 vaginal mesh repair for anterior vaginal wall
18 prolapse."

19 All right. Let's now, let's go to the
20 abstract. "We determined the efficacy of the use of a
21 tension-free Prolene mesh," this is the heavyweight
22 with the really small pores, "to correct a grade III
23 anterior vaginal wall prolapse recurrence."

24 Correct? Did I read that right?

25 A You read it right.

1 Q Under "Methods," "12 women (mean age 65.6
2 years) with stress urinary incontinence (SUI) four type
3 II and one type III and bladder prolapse entered the
4 study. After vaginal incision, a pretailored
5 polypropylene mesh was fixed," and they go into the
6 exact technique of how they do it.

7 So then we go down to "Results," and we
8 see, "All patients were available for postoperative
9 pelvic examination at three-month intervals for a mean
10 follow-up of 20.5 months."

11 So what they are telling us there is, after
12 putting the mesh in, the doctors then went in and did a
13 pelvic examination of the women. Correct?

14 A Please, again?

15 Q Is that right?

16 A Please, again? I was still busy to read this.

17 Q Quite all right, sir. I'll be glad to
18 rephrase it.

19 It says that, "All patients were available
20 for postoperative pelvic examination at three-month
21 intervals for a mean follow-up of 20.5 months."

22 My question is, that means that the women
23 had pelvic examinations after having the mesh
24 implanted. Correct? That's what postoperative means?

25 A That is correct, yes, yes.

3518

1 Q And then we see here, "No significant
2 postoperative pain was reported by the patients."
3 Correct?

4 A That is correct.

5 Q And under the "Conclusion" it says, "This
6 study confirms that in patients with moderate cystocele
7 a tension-free mesh to support a bladder base and neck
8 effectively treats the cystocele. It is particularly
9 recommended in the treatment of previous failure with
10 traditional techniques and when the quality of
11 suspending tissue is poor or defective"; is that right?
12 Did I read that correctly?

13 A You did. Yeah, you read it correctly.

14 Q Now, sir, you mentioned earlier -- you can
15 take that down.

16 You mentioned earlier, sir, that I think
17 the amount of the mesh --

18 Ben, do you have the Prolift?

19 I'll ask the jury to remember the Prolift
20 mesh.

21 THE COURT: You don't have it in the
22 courtroom?

23 MR. GAGE: He said he has got it back at
24 the war room.

25 THE COURT: Both sides refer to their rooms

1 as war rooms. Just so you know, it's equal.
 2 MR. GAGE: Not that we're at war or
 3 anything.
 4 THE COURT: Both plaintiffs and defendants
 5 call it that. We can proceed.
 6 If you need the mesh, we can get it.
 7 MR. GAGE: I don't, Judge. It's not that
 8 big of a deal.
 9 THE COURT: All right. Go ahead.
 10 MR. GAGE: The jury is going to get to see
 11 a good bit of it, so...
 12 BY MR. GAGE:
 13 Q Sir, you were talking about the amount of
 14 the polypropylene mesh in the implant.
 15 Do you remember that? And I think you
 16 referenced four football fields?
 17 A Yeah.
 18 Q Hernia meshes are sometimes -- how big --
 19 what's the biggest hernia mesh you ever implanted, sir?
 20 Maybe as big as that sheet of paper?
 21 A This is Din A4. It is 30 to 20 --
 22 Q Maybe even bigger than that?
 23 A Bigger than this.
 24 Q Bigger than that. All right.
 25 So you've implanted meshes in people's

3520

1 abdominal space that are bigger than that sheet of
 2 paper. Correct?
 3 A But it's a completely different thing.
 4 Q Totally different things?
 5 A Yes.
 6 Q You've got one in the pelvis and one in the
 7 abdomen. And I'm not trying to suggest they're one and
 8 the same, sir. I'm just trying to ask you a couple
 9 questions.
 10 A Yep.
 11 Q You've put that amount of polypropylene
 12 inside human bodies. Correct?
 13 A Yes.
 14 Q And if we were to take that mesh and we
 15 were to lay it end on end, it would go a lot longer
 16 than four football fields, wouldn't it?
 17 A No. We have made at that time some calculations,
 18 and it was -- depending from the mesh you used, it was
 19 only 300 meters.
 20 Q Only 300 meters?
 21 A 300 meters, and -- yeah. So a little bit less.
 22 But it depends mainly from the textile structure. It
 23 doesn't make any sense to say how long. It is a huge
 24 amount of suture material.
 25 Q And that's what I want to talk to you

1 about, sir.
 2 Sometimes it's 300 meters and sometimes it
 3 may be 400 meters. Right?
 4 A Yes.
 5 Q Now, sir, when we talk about polypropylene,
 6 polypropylene mesh is currently the most utilized
 7 synthetic surgical material. Correct?
 8 A You read it or you stated it?
 9 Q I'm asking you whether it's a true
 10 statement, sir.
 11 A I think it is correct.
 12 Q Okay. Well, it was in your expert report.
 13 I was going to show it to you, but --
 14 A I didn't learn it by heart, so...
 15 Maybe we can read it.
 16 Q As long as you agree to it, sir, I don't
 17 need to read it.
 18 Polypropylene is favored for most mesh
 19 constructions. Correct?
 20 A Yes. Favored, yeah. It's used for...
 21 Q And polypropylene mesh is the most widely
 22 used material for hernia repair. Correct?
 23 A Yes.
 24 Q And polypropylene mesh is the most widely
 25 used material for pelvic floor repairs. Correct?

3522

1 A Yes.
 2 Q And 91 percent of all gynecological meshes
 3 sold in the United States are polypropylene. Correct?
 4 A Yes.
 5 Q And, sir, you would agree with me that
 6 polypropylene is appropriate for use in the pelvic
 7 floor if you have the right construction of the
 8 polypropylene. Correct?
 9 A If you have the right construction, yes.
 10 Q And mesh is an important option for
 11 patients in pelvic floor repair. Correct? You would
 12 agree with that?
 13 A I can imagine that there are some patients, even
 14 in the pelvic floor, but I'm not a specialist for
 15 finding the best indication for a mesh in this area. I
 16 know from the abdominal wall that there is -- since 20
 17 years, we have a lot of discussion, it is changing what
 18 is the best indication for these meshes, and there are
 19 areas where it's not an accepted indication to today.
 20 Q All right. Now, sir, I want to go back for
 21 just a few minutes into your background and your
 22 history as a hernia surgeon. When I read your
 23 deposition, you know, obviously I was not the one
 24 coming over to Germany to take your deposition, but
 25 I've read your deposition. And I think you told us

1 then that you had implanted meshes, many of which were
2 polypropylene meshes, into something in the
3 neighborhood of about 300 patients.

4 Does that sound about right?

5 A Yes.

6 Q Now, hernia surgeries are one -- I think I
7 read it's the most commonly performed surgical
8 procedure every year; is that right?

9 A For abdominal surgery, yeah. It's the most often
10 performed procedure.

11 Q And in your deposition, I think you told us
12 that 20 million meshes are implanted each year for
13 hernia repair?

14 A The older figures are -- in US it's about 1
15 million, maybe worldwide maybe 2 million, and I was a
16 little bit surprised. This came from a recent
17 publication from around Kingsnorth, and there it was
18 mentioned 20 million meshes, but they didn't specify
19 for what purpose.

20 Q So a good portion of those are probably
21 polypropylene. Correct?

22 A Yes.

23 Q So if we're getting 20 million people a
24 year -- and let's just say, what, 10 million of them
25 are polypropylene or have polypropylene in it, would

1 Q It doesn't matter.

2 If you look over a 10, 15 or 20-year window
3 of time, we're talking about certainly tens of millions
4 of people on this planet are walking around with meshes
5 in their body, and a large percentage of those meshes
6 are either polypropylene or they contain polypropylene.
7 Correct?

8 A Yes. But you are aware that you mix up a lot of
9 different indications, materials and all this.

10 Q Correct. And we're going to get to some of
11 that.

12 Now, one of the reasons that you and many,
13 many other surgeons like you have used polypropylene
14 meshes and other meshes is because, if you take a
15 person who's got a hernia -- and, sir, I have to
16 confess, before I got involved in this lawsuit, I was
17 not an expert on hernias, but they can be significant
18 and they can be serious. Correct?

19 A It was a complex question. Please, can you make
20 it --

21 Q Yes.

22 Hernias can be --

23 A I have to translate it.

24 Q Hernias can be a serious condition.

25 Correct?

1 that be a fair estimate, or would you say the number is
2 higher than that?

3 A I cannot say. There aren't any data about it.
4 But I would rely to the 2 million that are treated with
5 meshes for abdominal wall. And, yeah, maybe there are
6 5 million, 6 million, but...

7 Q With polypropylene?

8 A With polypropylene.

9 Q And that's a year, per year. Right?

10 A That is -- would be the present status maybe.

11 Q So we're talking about a lot of people
12 around the world?

13 A Yes. It's an important problem.

14 Q Tens of millions?

15 A Yes.

16 Q Potentially hundreds of millions?

17 A I wouldn't go so far.

18 Q Well, if you said 20 million a year --

19 A He said 20 million a year. And I told you that I
20 think this is a -- but if you're looking to the
21 Chinese, maybe we will get completely other, and India.
22 So we are all small countries, even this one.

23 Q So long story short is, whether 20 million
24 is right or 5 million is right, if you look over --

25 A It doesn't matter.

1 A Yes.

2 Q And surgeons sometimes try -- essentially
3 it's an organ, maybe a piece of the abdomen, perhaps,
4 that pushes through the abdominal wall?

5 A Yes.

6 Q And you need to be able to put that organ
7 back so that the person doesn't have a more serious
8 condition, such as the abdominal wall cutting off the
9 blood flow to that particular organ. Correct?

10 A That can happen, yes.

11 Q And that can kill you. Correct?

12 A That can kill you, yes.

13 Q So one option the surgeons have, and at
14 least in the hernia space, is to just simply use
15 sutures, like we were talking about, stitches where I
16 come from, where you stitch up, you open up the abdomen
17 and you push the organs back in and then you can stitch
18 it up. Correct?

19 A Yes.

20 Q And then another option is the use of a
21 mesh. Correct?

22 A That is correct.

23 Q And one of the reasons that surgeons use
24 the meshes in the hernia space is because of
25 recurrence. Correct?

1 A That is one aspect. However, we have -- since
2 I'm in -- working in this field of abdominal wall
3 hernia, every year we have several conferences with
4 lots of discussions about when to do, what to do. And
5 so...

6 Q Right.

7 A I think it is too simple to say, there is a
8 hernia and you do it because of the recurrence. This
9 is too short.

10 Q Well, one of the reasons -- well,
11 reinforcement of tissues with mesh implants is
12 definitely the treatment of choice due to reports of
13 low recurrence rates.

14 Do you agree with that?

15 A Yeah.

16 Q Ease of use. Correct? Ease of use.
17 Correct?

18 A Ease of use? The ease of use, yeah, yeah, yeah.

19 Q And low morbidity rates. Correct?

20 MR. ANDERSON: Objection, Your Honor.

21 May we approach, Your Honor?

22 THE COURT: Okay.

23 - - -

24 (The following occurred at sidebar:)

25 MR. ANDERSON: Your Honor, we object. It's

1 far beyond the scope. One of the things that I know
2 that Mr. Mazie and Mr. Slater told you on Friday was
3 that we were going to try to severely limit the areas
4 of questioning that we went into. I cut out hours of
5 things, and one of the things that I strictly tried to
6 stay away from was getting into the history of hernia
7 surgery, all of the various things about hernia
8 surgery, the indications, the types of materials,
9 because we could be here three days. And if I come
10 back on redirect, we will, because I have mounds,
11 mounds of hernia stuff that we can get into. And I
12 didn't think we were going to do that. I thought we
13 were going to talk about the Prolift.

14 I realize there is a little bit of
15 crossover, and he's gone through a half hour of the
16 history of that. But now we're getting into, there are
17 parastomal hernia, there are esophageal hernia, there
18 are all kinds of abdominal surgeries. We could go on
19 with this forever.

20 And I thought that what we were trying to
21 do is finish this today, if we could, and we never will
22 like this, because he has gone so far down, and if he
23 keeps going down this road, Your Honor, I have got to
24 come back, because there are vast differences between
25 hernia and pelvic organ prolapse. Vast differences.

1 And it is an enormous load, because as he's already
2 said, 50 years on that. Marlex alone we could go into
3 forever.

4 You saw, Your Honor, that I specifically
5 stayed on Prolift. I didn't talk about Ultrapro, I
6 didn't talk about Marlex, I didn't talk about Prolene.
7 I stayed away from it. But I could easily go there.
8 And there's plenty of great stuff I could go into, but
9 we will be here for a couple of days. And I have an
10 opportunity, if he's going to keep going down this
11 road, to go down that road. This is a huge area of
12 medicine.

13 MR. GAGE: Your Honor, I have, I'm guessing
14 five to seven more minutes based on his own experience,
15 which happened -- unfortunately, happens to be only in
16 the hernia space. And then I don't think -- I don't
17 think we're going to be dealing specifically with
18 hernia thereafter. I mean, obviously there's some
19 things that relate to hernias, but that's not --

20 THE COURT: Well, I'm not going to limit
21 you. I think that it's relevant and it's within the
22 scope of the direct, even though it's a different
23 branch of the direct, but it is in fact relevant to
24 what he's testified to, which is generally whether this
25 material is safe. I know he's indicated it's safe for

1 one thing. Certainly the defense can bring out that
2 he's used the material, that other people have used the
3 material, that it's been around for a long time.

4 I personally would love to shorten the case
5 as much as possible and avoid two days on the stand
6 with this man, but I don't think that I can
7 legitimately curtail the defense from going into some
8 issues, and then you are going to have to make your
9 call of what you need to go into.

10 MR. ANDERSON: Certainly.

11 - - -

12 (The sidebar ended.)

13 - - -

14 BY MR. GAGE:

15 Q So, Doctor, we were talking about the
16 surgeries that you were performing in the hernia space.

17 And I think we established that it was
18 something in the neighborhood of 300 patients.
19 Correct?

20 A Yeah.

21 Q And I know, I think from your deposition
22 you indicated that you implanted Marlex mesh, one of
23 the ones we looked at earlier, in some of your
24 patients. Right?

25 A Yes, yes.

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1 Q And that's a polypropylene mesh. Correct?
 2 A Yes.
 3 Q And Atrium, that was the name of a mesh --
 4 A Yes.
 5 Q -- I think you implanted in some patients.
 6 Is that a polypropylene mesh?
 7 A Yes.
 8 Q And then Prolene, that's an Ethicon mesh?
 9 A Yes.
 10 Q And it's made out of polypropylene.
 11 Correct?
 12 A Yes.
 13 Q And you implanted that in some of your
 14 patients?
 15 A Yes.
 16 Q And Ultrapro, that's a partially --
 17 A A mixed.
 18 Q It's a mix.
 19 It's got polyglactin and it's also got
 20 polypropylene in it. Correct?
 21 A Yes.
 22 Q I think you implanted that mesh in 150 of
 23 your patients. Right?
 24 A Yes.
 25 Q And that's an Ethicon product. Right?

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1 A (Witness nods head.)
 2 Q Now, sir --
 3 A But, you know, it never -- it's used for
 4 laparoscopic incisional hernia repair. There it's
 5 forbidden to use any unprotected polypropylene mesh to
 6 place it underneath.
 7 So these are all open surgeries. It is a
 8 failure in our field if you are using polypropylene
 9 meshes in the abdominal cavity.
 10 Q And, sir, in the 1980s and then in the
 11 1990s and then all the way up to 2005 or '6 when you
 12 stopped doing surgery --
 13 A 2006.
 14 Q -- 2006, you knew that all of these
 15 surgical meshes that you were implanting carried
 16 certain risks. Correct?
 17 A Yes.
 18 Q And that would include the risk of
 19 infections?
 20 A Yes.
 21 Q And the risk of chronic pain?
 22 A Yes.
 23 Q And the risk of adhesions?
 24 A Yes.
 25 Q And the risk of mesh shrinkage?

1 A Any operation carries some, yeah.
 2 Q And you knew that there was a potential
 3 risk for mesh erosion?
 4 A Yes.
 5 Q And, sir, I'm not trying to trick you, I'll
 6 tell you I'm coming right out of your expert report on
 7 this one, page 28.
 8 You remember talking about foreign body
 9 reaction and chronic inflammation on your direct exam
 10 earlier this morning?
 11 A Yes.
 12 Q Remember we talked about that?
 13 A Yeah.
 14 Q Talked about fibrotic bridging, where the
 15 scar tissue builds around the pores --
 16 A Yes.
 17 Q -- and causes problems for the patient?
 18 A Yes.
 19 Q It's a well-known fact and all the studies
 20 indicate that all mesh products on the market today
 21 cause an initial and chronic inflammatory tissue
 22 response in the recipient after implantation. Correct?
 23 A That's what we found out and published.
 24 Q Every single one of them?
 25 A Yes. But it doesn't say anything about the

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1 extent.
 2 Q And, sir, when you were putting the meshes
 3 in your patients, the 300 patients, you knew about all
 4 of these risks, but you implanted them nonetheless
 5 because you believed the benefits of the mesh
 6 outweighed the risks. Correct?
 7 A It's always a very careful decision whether to
 8 make it or not. It depends from the patient, from the
 9 age, from the location, from this analysis of the
 10 individual risk balance that can be done. And as I
 11 told you, that is a permanent discussion at our
 12 conferences every year, ours.
 13 Q Yes. And, sir, the reason that it's a
 14 permanent discussion at all of your meetings and the
 15 reason you've been discussing it since 1995 is because
 16 no perfect mesh has been built yet, has it?
 17 A It is well agreed by all of my colleagues that
 18 there will be never a perfect mesh that fulfills all
 19 these requirements. There will be no serious
 20 researcher or surgeon who will claim that there will be
 21 one ideal mesh for every purpose. It is not
 22 imaginable.
 23 Q Sir, let's -- I'm handing you an article
 24 marked Defendant's Exhibit DLTB00045.
 25 Have you looked at that, sir?

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1 A I don't recall exactly. Maybe.
 2 Q And up here at the top, International
 3 Journal of Urology.
 4 And that's 2012. Correct?
 5 A Correct.
 6 Q And, again, sir, this would be a journal
 7 that you do not subscribe to. Correct?
 8 A Yes.
 9 Q "Pelvic organ prolapse transvaginal repair
 10 by the Prolift system: Evaluation of efficacy and
 11 complications after 4.5 years of follow-up."
 12 Did I read that right?
 13 A Yes.
 14 Q Let's go to page 45.5. And kind of pull
 15 that block out.
 16 Sir, what we've got is kind of a summary of
 17 previous literature with regard to the Prolift.
 18 Correct?
 19 A Yes, that's right.
 20 Q And so what the author of this study is
 21 doing in 2012 is looking back in time at a number of
 22 other peer-reviewed publications published by other
 23 pelvic floor surgeons and doctors. Correct?
 24 A That is correct.
 25 Q And we've got the author over here. Right?

3536

1 And we've got the number of patients. Correct?
 2 A That is correct.
 3 Q So here we've got 75 in this one, 526, 254,
 4 127, all the way down here to 323. Correct?
 5 A Yes.
 6 Q And they're all getting the Prolift except
 7 we got one Prolift+M. Correct?
 8 A That is correct.
 9 Q And then these are the different types of
 10 Prolifts. These are either the anterior, the
 11 posterior, or the total. Correct?
 12 A Yep.
 13 Q This is how far out they're coming back and
 14 checking in with the women. Right?
 15 A Right.
 16 Q So in this one, for example, the mean
 17 follow-up, kind of like the average, I know that
 18 average and the mean aren't exactly the same, but
 19 bottom line, average/mean means about the same thing.
 20 Right?
 21 A Better would be the median.
 22 Q I knew I was going to get that. The
 23 median, 54 months.
 24 But essentially, bottom line is they're
 25 going in -- 54 months is what?

1 A It gives an estimate that they -- it's not two
 2 months, it's longer.
 3 Q It's not two months. They go in something
 4 like four-and-a-half years after they got the Prolift,
 5 and then they looked at cure rate and mesh exposure; is
 6 that right?
 7 A Yep.
 8 Q So when we look at the cure rate, we see
 9 81.5. And when we talk about anatomical cure rate,
 10 we're talking about fixing the prolapse. Correct?
 11 Repairing the prolapse?
 12 A I'm aware that there is a big discussion, what is
 13 the best readout, is it the anatomical, is it
 14 functional, is it -- yeah.
 15 MR. ANDERSON: Objection, Your Honor. May
 16 we approach?
 17 - - -
 18 (The following occurred at sidebar:)
 19 MR. ANDERSON: Judge, he didn't go into any
 20 of this literature on his direct. He's only a
 21 materials expert. He hasn't got into success rates,
 22 recurrence rates.
 23 THE COURT: I think this is beyond his
 24 expertise, as far as just talking about how often it
 25 cures the problem. He's indicated he is not a surgeon

3538

1 who ever has done this. He doesn't prescribe to these.
 2 MR. GAGE: There's a very specific point
 3 that I want to go to.
 4 THE COURT: What's that?
 5 MR. GAGE: That is that the Prolift+M,
 6 which has the larger pores than does Prolift, has a
 7 lower cure rate and a mesh exposure rate that is
 8 basically the same.
 9 MR. MAZIE: He hasn't gone into Prolift+M.
 10 MR. ANDERSON: We specifically didn't go
 11 into Prolift+M. Plus he doesn't subscribe to these.
 12 He's not a urogyn. You did a great job of saying what
 13 he doesn't do and what he hasn't reviewed. These would
 14 be great for urogynecologists. You had your chance
 15 with Weber would be my position, respectfully.
 16 This guy is a biomaterials science
 17 researcher, abdominal surgery. You went into it, you
 18 said you have five to seven more minutes. If you want
 19 to start to get into studies, clinical studies, RCTs
 20 and comparative trials, that's already been gone into
 21 in this case.
 22 THE COURT: Well, if you want to ask him if
 23 the Prolift+M has larger pores, you can certainly
 24 establish that through this witness. But the success
 25 rate as far as -- and he's indicated he doesn't know

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1 whether we're talking functional success rate,
2 anatomical success rate. It's not within his
3 expertise. You can ask him if there's larger pores.
4 And then you can bring the study up with one of your
5 witnesses. I'm sure you will.

6 MR. ANDERSON: Thank you, Your Honor.

7 - - -

8 (The sidebar ended.)

9 - - -

10 BY MR. GAGE:

11 Q Jamey, let's put that back up.

12 Now, sir, the point of putting this up here
13 is to go to Prolift+M.

14 That is actually the Ultrapro material.

15 Correct?

16 A Yes, that is correct.

17 Q And the Prolift+M has larger pores than the
18 Prolift. Correct? Or the Ultrapro has the larger
19 pores than the Gynemesh PS. Is that fair to say?

20 A This is not true with strain. Without strain,
21 this is true. But if you apply some strain, it is not
22 true.

23 Q What about without strain?

24 A Without strain, yes.

25 Q It's got larger pores?

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1 A Larger pores.

2 Q You can take that down.

3 Let's put up Plaintiffs' Exhibit -- or
4 PLT0261.

5 Sir, you remember, I think you talked about
6 this article this morning. Do you remember that?

7 A Yes.

8 Q And I think this was the article where you
9 indicated it was -- let's just look at the title here.

10 "Shrinking of polypropylene mesh in vivo: An
11 experimental study in dogs." Right?

12 A That is right.

13 Q That's one of your studies, Uwe Klinge.
14 Correct?

15 A Yes.

16 Q I think we came down here, you mentioned
17 something about meshes that contain a lot of
18 polypropylene shrink to about 30 to 50 percent of their
19 original size. Correct?

20 A Yes.

21 Q Now, sir, this study, if I understand it,
22 did not involve Gynemesh PS or Prolift. Correct?

23 A That is correct.

24 Q You take that down, and let's put up
25 Defendant's Exhibit 372.

1 Sir, I'm handing you a copy of Defendant's
2 Exhibit 372. Give you just a second to look that over.

3 That's an internal e-mail from Ethicon.

4 Correct?

5 A It appears to be so, yes.

6 Q And you looked at a lot of internal
7 documents. Correct?

8 A Yes.

9 Q Correct?

10 A Yes.

11 Q And was this one of the ones that you
12 looked at?

13 A No.

14 Q I'm sorry?

15 A No.

16 Q You never saw this document?

17 A The first page, not. I'm --

18 Q I'm sorry, go ahead and take your time to
19 read it, and then I'm going to ask you, have you seen
20 this document before.

21 A Yes.

22 Q Sir, I'm not going to quiz you on the
23 details, just kind of big picture.

24 Do you remember --

25 A No, I have never seen it.

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1 Q You've never seen it?

2 A No.

3 Q So I'm not going to read the whole thing to
4 you, sir, because it's pretty lengthy, but, Jamey,
5 let's start here in the middle where it's from Cosson.
6 Yeah, right there. All right.

7 So you know Dr. Cosson or you're familiar
8 with him from looking at your documents. Correct?

9 A Yes.

10 Q He was one of the doctors I think that was
11 in on the ground floor of Prolift. Is that fair to
12 say?

13 A Yes.

14 Q And I think he was -- I think he was
15 involved in the TVM studies. Correct?

16 A Yes.

17 Q So he was there from the very beginning.
18 Correct?

19 A If you -- yeah.

20 Q So here he is e-mailing somebody at ETHUS.
21 And you understand that to be Ethicon US.

22 Right?

23 A Yes, uh-huh.

24 Q And the date is February 25, 2004.

25 Correct?

1 A Yes.
 2 Q That is almost one year before Prolift goes
 3 on the market. Correct?
 4 A Yes.
 5 Q And he says, "Joshua." And just so we get
 6 things clear, I think he's from France. Right?
 7 Dr. Cosson?
 8 A I think so as well, yeah.
 9 Q And you're from Germany, and sometimes
 10 e-mails don't get quite typed the way that people that
 11 speak English read it. So you may see some stuff in
 12 here that doesn't quite make sense, but he says, "I
 13 join you the answers. I apologize for the delay.
 14 Sincerely yours, Michel." Right?
 15 A You read it right.
 16 Q So let's go to the next page. And let's
 17 look at question number 7. "Is it critical that mesh
 18 straps lay flat in channel or is it ok to be
 19 rolled-up?" And Dr. Cosson says, "If the mesh is in
 20 place, there is no problem for a roll-up."
 21 Do you see that?
 22 A Yes. This is evidence to class level 5, evidence
 23 level 5. It's just expert, meaning no data.
 24 Q You can take that down.
 25 Now, sir, we talked about -- you talked

3544

1 earlier about fibrotic bridging?
 2 A Yes.
 3 Q Where things build around the scar or build
 4 around the mesh and form a scar plate. Right?
 5 A Filling out the pores.
 6 Q Filling out the pores.
 7 And that's not a good thing --
 8 A No.
 9 Q -- in your opinion?
 10 A Yeah. In most of the indications, if you made a
 11 replacement of a knee ligament, maybe it's different.
 12 It depends.
 13 Q So on this subject, I'm going to hand you
 14 Defendant's Exhibit DLTB00266.
 15 Do you see that?
 16 A Yes.
 17 Q That is something -- that is a document you
 18 have seen before. Correct?
 19 A Yes, I have seen it.
 20 Q And you've seen it because you wrote it.
 21 Right?
 22 A Yes.
 23 Q All right. So the title of it is, "The
 24 lightweight and large porous mesh concept for hernia
 25 repair." Correct?

1 A Yes.
 2 Q And I think you talked about Dr.
 3 Klosterhalfen earlier?
 4 A Yes.
 5 Q And you and he are co-authors on this
 6 document. Correct?
 7 A Yes.
 8 Q Let's go to the bottom so we can get a date
 9 on it.
 10 And this is 2005. Correct?
 11 A Yes.
 12 Q And, sir, let's flip over, it's page 105 of
 13 the article, the reference number is Defendant's
 14 LT266.3.
 15 Do you see that?
 16 A Yes.
 17 Q And there's a header there called
 18 "Integration into the abdominal wall biocompatibility."
 19 Correct?
 20 A That is correct.
 21 Q When we talk about biocompatibility, I know
 22 you probably have a lot more technical definition than
 23 I can articulate, but as I understand it, it is
 24 basically how well is the mesh going to do inside the
 25 human body?

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1 A That is maybe your definition.
 2 Q Well, that's what I said. That's just kind
 3 of a big picture definition.
 4 Biocompatibility is how the body reacts to
 5 the mesh once it's implanted?
 6 A It includes two parts. First is the function, so
 7 you use this term to describe whether it has a good
 8 biocompatibility or a bad. Therefore, we use this
 9 term. And one aspect is always the function, whether
 10 it's able to preserve to reconstitute the function, and
 11 the second is whether this is combined with added
 12 tissue damage to this.
 13 Q Okay.
 14 A And, therefore, it depends very much from the way
 15 you use it. You cannot say that something has a
 16 biocompatibility -- a high biocompatibility for any
 17 purpose. That would be the same as if you are looking
 18 for the ideal mesh for every purpose.
 19 Q But can we agree that biocompatibility --
 20 we want our meshes to be biocompatible?
 21 A I hope so.
 22 Q Right. I mean, biocompatibility, when we
 23 talk about having good biocompatibility, that's a good
 24 thing for the patient. Correct?
 25 A Yes, if --

1 Q And when we talk about bad
2 biocompatibility, that's a bad thing for the patient.
3 Correct?
4 A Yes.
5 Q Now, let's go down to the bottom of the
6 beginning of this second paragraph. "Today, it is not
7 fully clear why inert and nonimmunogenic materials
8 induce this type of inflammation known as foreign body
9 reaction (FBR)."
10 And, sir, I think you talked about foreign
11 body reaction when you were up here, when Mr. Anderson
12 was asking you questions?
13 A Yes.
14 Q And foreign body reaction and
15 biocompatibility are related notions?
16 A It has to be considered, of course.
17 Q But, I mean, in other words, foreign body
18 reaction and biocompatibility are more or less the same
19 thing?
20 A No, no, definitely not. Because a foreign body
21 reaction, you always have -- you always -- you
22 cannot -- there is hardly any situation where you don't
23 have the macrophages around the foreign body.
24 Q That's with every mesh?
25 A Yes. Therefore, a foreign body reaction, you

3548

1 always have it.
2 Q Correct.
3 A But the extent of foreign body reaction, this is
4 important for the function later on. And, therefore,
5 we are coming back to the design for the function for
6 the purpose where to place it.
7 Q Right. And what I meant --
8 A But foreign body is a completely separate thing.
9 Q What I meant I think -- you have a
10 scientific mind and I don't. I didn't mean it quite at
11 that level. I think what my --
12 A Therefore, I'm sitting here and you're standing
13 there.
14 Q That's exactly right.
15 A Yes.
16 Q What I mean is that biocompatibility and
17 foreign body reaction both, at a very high level, deal
18 with concepts of the mesh once it's inside the body.
19 Correct?
20 A I didn't understand this question clearly. There
21 is -- as I told you --
22 Q I tell you what, let's keep going. I think
23 we'll be able to solve our problem as we keep reading
24 through this document.
25 A I'm sure. It's not helpful to stick to this.

1 Q Okay. "So today it is not fully clear why
2 inert and nonimmunogenic materials induce this type of
3 inflammation known as foreign body reaction (FBR)."
4 That's what you just discussed, right, FBR?
5 A We discussed foreign body reaction. This
6 sentence means that we don't know at a genetic and
7 molecular level what exactly happens. You always saw
8 these macrophages, but what goes in detail there, we
9 know a lot of molecules today, so there are some --
10 there has to be done a lot of research to understand
11 this better. This is what this sentence is expressing.
12 Q So let's go to page 111 of the article,
13 which is Defendant's Literature 266.9. And let's
14 highlight the first couple of sentences -- or let's go
15 up to this fibrotic bridging section.
16 Sir, I believe you talked briefly about
17 fibrotic bridging. Do you recall that?
18 A What?
19 Q I believe you talked earlier about --
20 A Yes.
21 Q -- fibrotic bridging?
22 A Yeah, sorry. I read it already.
23 Q Oh, that's fine.
24 So we see up here, "Fibrotic bridging is a
25 phenomenon which is, in the author's opinion" -- and

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1 that's you. Correct? You and others?
2 A Yes.
3 Q -- "closely associated with the occurrence
4 of shrinkage."
5 We've talked about shrinkage, haven't we?
6 A Yes.
7 Q "Moreover, the incidence of bridging is
8 unrelated to the textile structure of the mesh."
9 That's what that sentence says. Correct?
10 A Yeah.
11 Q And then it says, "Bridging occurs in all
12 mesh modifications with a granuloma size around each
13 mesh fiber exceeding more than half of the pore size of
14 the mesh." Correct?
15 A Yes.
16 Q Now, Jamey, if we could, let's pull out and
17 go to the next column on the same page under the
18 heading --
19 A The next sentence would be helpful.
20 Q No, no, no. Down here to "Chronic pain."
21 There we go.
22 All right. So -- and, sir, you talked
23 about -- I think you talked about pain earlier this
24 morning. Correct?
25 A Yes.

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1 Q And chronic pain means pain that keeps
2 going. Right?

3 A Yes.

4 Q It doesn't go away?

5 A Yes.

6 Q "In contrast to neuropathy-related
7 complaints after intraoperative damage of nerve fibers
8 with pain immediately after surgery," and I want to
9 pause there before we finish the sentence.

10 What we're talking about there, sir, is
11 during the operation, the patient has some nerve fibers
12 that are damaged, and that leads to pain after -- right
13 after the surgery. Right?

14 A It can, yeah.

15 Q So in contrast to that kind of pain, the
16 onset of chronic pain as a consequence of the
17 fibrotic -- of the FBR is typically more than one year
18 after hernia repair?

19 A In the groin.

20 Q That's what you've got right there.

21 Correct?

22 A Uh-huh.

23 Q Sir, we talked about -- I should say you
24 talked about. We talked about that -- we talked about
25 some of the testing on the mesh. Do you remember that?

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1 A Yes.

2 Q And we talked about uniaxial and
3 multiaxial. Do you recall that?

4 A Yes.

5 Q I'm going to hand you an article here, it's
6 Defense or DLTB00139.

7 Sir, you've seen this article before.

8 Correct?

9 A Yeah, I've seen it.

10 Q This article comes out in 2005. Correct?
11 So it's 2005. Correct?

12 A Yeah, that is correct.

13 Q And these are a number of surgeons in
14 Belgium out of the department of obstetrics and
15 gynecology. Correct?

16 A That is correct.

17 Q So let's go over -- let's go to the next
18 page.

19 Do you see that header down there,
20 "Synthetic implants"?

21 A Yes.

22 Q All right. So "Polypropylene mesh became
23 the most commonly used synthetic prosthesis. Simple
24 synthetic filaments, yarns, are used to manufacture
25 these implants. There is, however, considerable

1 variation of fiber diameter, knotting or weave

2 configuration and size of pore and/or interstices.

3 Meshes can be made from knitted single

4 fiber-filaments," which they called monofilament

5 materials, "or they can be braided with monofilament

6 yarns, further woven as multifilament fibers in

7 different ways and pore sizes."

8 Now, sir, Gynemesh PS, going back to

9 Gynemesh PS, is it a knitted fabric?

10 A I think it would be named as a knitted fabric,
11 yeah.

12 Q And it's a monofilament?

13 A The term or the naming of monofilament has its
14 limitation. The filament that is used is a
15 monofilament instead of a multifilament. But at the
16 knots, it is a multifilament or oligiofilament
17 structure because that means that the filaments are
18 coming close together.

19 Q So now let's go up to Figure 1. And let's
20 just start here where it says, "Knitted fabrics." It
21 says, "Knitted fabrics have a more open structure than
22 woven. The knit construction allows the mesh to be
23 stretched in both directions to accommodate and
24 reinforce tissue defects. Fabric is produced in such
25 fashion as to interconnect each filament yarn and

3554

1 provide bidirectional elasticity, while allowing the
2 mesh to be cut to any shape without loosening yarns."

3 Did I read that correctly, sir?

4 A You read it correctly, yeah.

5 Q Thank you.

6 MR. GAGE: All right. Judge, I'm about to
7 do a big shift.

8 THE COURT: Let's take a break.

9 MR. GAGE: Okay.

10 THE COURT: We'll take a 10- or 15-minute
11 break.

12 - - -

13 (The jury leaves the courtroom.)

14 - - -

15 (A recess was taken from 2:36 p.m. to
16 2:58 p.m.)

17 - - -

18 THE COURT: You can bring the jury in.

19 - - -

20 (The jury enters the courtroom.)

21 - - -

22 THE COURT: You can be seated and you can
23 continue, Mr. Gage.

24 MR. GAGE: Thank you, Your Honor.

25 BY MR. GAGE:

1 Q Dr. Klinge, I'm handing you a copy of
 2 the -- this is your effective porosity article. The
 3 jury has seen it a number of times. Jamey, let's put
 4 it up. I've got it as PLT0346.
 5 Dr. Klinge, the jury has heard Dr. Muhl.
 6 Have you read Dr. Muhl's testimony?
 7 A Yes.
 8 Q So you know what he's already told the
 9 jury?
 10 A This testimony here? No, I didn't get it.
 11 Q Well, I'm not going to cover every single
 12 aspect of the testing, because we covered a lot of that
 13 with Dr. Muhl, so I didn't want you to feel like I was
 14 leaving out some portions and asking you only about
 15 others, but we covered a good bit of it. I want to
 16 just kind of hit the stuff that --
 17 A I'm happy with it.
 18 Q That's good.
 19 So bottom line is -- well, the first thing
 20 I want to establish is you didn't publish this until
 21 2007. Right?
 22 A Yes.
 23 Q And that's when the results of this new
 24 objective measurement, I mean, that's when it went out.
 25 Right? 2007?

3556

1 A Yes.
 2 Q And you're one of the authors. Right?
 3 Along with Dr. Muhl?
 4 A Yes.
 5 Q Now, let's go to -- it's one, two, three,
 6 four -- it's the fifth page, Jamey. And there's
 7 Table 1 at the bottom of that page.
 8 Dr. Klinge, you remember Table 1? Do you
 9 see that?
 10 A Yes, I see it.
 11 Q Now, you tested four meshes, Optilene,
 12 Sofradim, TiMesh and DynaMesh. Right?
 13 A Yes.
 14 Q Just so the jury follows where we're going,
 15 this is the testing you did in 2007, not the testing
 16 you did of Prolift in 2012. Right?
 17 A Yes.
 18 Q Now, Optilene, if we go over here on the
 19 table, had 0 percent effective porosity. Correct?
 20 A Yes.
 21 Q And I think you said that's because none of
 22 the pores were larger than 1 millimeter. Right?
 23 A Yes.
 24 Q And we've talked a lot about 1 millimeter
 25 and we've also talked about 75 microns. And the jury

1 is going to probably see some things that talk about
 2 1,000 microns. So let's get everybody accustomed to
 3 what we're talking about.
 4 As I understand it, 1 millimeter is how
 5 many microns?
 6 A 1,000.
 7 Q So 1 millimeter is 1,000 microns?
 8 A Yes.
 9 Q And so when you did the testing here, you
 10 did the same thing that you did with the Prolift
 11 testing -- to the Prolift mesh in 2012. Right?
 12 A Yes.
 13 Q I mean, it's the same testing. Right?
 14 A Yes.
 15 Q Same testing method?
 16 A Yeah.
 17 Q And you looked at the mesh. And using
 18 cameras and a computer, you counted the number of pore
 19 spaces that were larger than 1 millimeter. Correct?
 20 A Yes.
 21 Q And if the mesh doesn't have a pore size
 22 that's larger than 1 millimeter, it's got 0 percent
 23 effective porosity. Correct?
 24 A Yes.
 25 Q So Sofradim was another mesh, and it had a

3558

1 29 percent effective porosity. Right?
 2 A Yes.
 3 Q And TiMesh light had 0 percent effective
 4 porosity?
 5 A Yes.
 6 Q And DynaMesh polypropylene light had
 7 42 percent. Correct?
 8 A Yes.
 9 Q So DynaMesh basically won the kind of best
 10 in show, right, at least for purposes of your testing.
 11 Correct?
 12 A I would object to the term "won."
 13 Q Fair enough. It had the best effective
 14 porosity of any of the four meshes that you tested?
 15 A Yes.
 16 Q Now, you also tested a DynaMesh mesh in
 17 2012 when you tested the Prolift mesh. Correct?
 18 A Yes.
 19 Q And it was a pelvic floor mesh?
 20 A Yes.
 21 Q It's made of a different material called
 22 PVDF. Correct?
 23 A Yes.
 24 Q If I remember the wording from your expert
 25 report, you said that the DynaMesh mesh had excellent

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3561

1 porosity -- I'm sorry, excellent effective porosity.
 2 Correct?
 3 A It has a higher, because it has a higher
 4 structural stability, yes.
 5 Q So when we ran the 2012 test, we had a
 6 DynaMesh mesh and we had one made by Ethicon. And the
 7 DynaMesh test or the DynaMesh mesh in 2012 had the
 8 higher effective porosity. Correct?
 9 A Yes.
 10 Q Now, DynaMesh is manufactured by a company
 11 called FEG. Right?
 12 A Yes.
 13 Q And they're in Aachen. Right?
 14 A Yes.
 15 Q They're a German mesh maker?
 16 A And they made the Vypro for Ethicon at that time.
 17 Q And I think you're a paid consultant to
 18 FEG?
 19 A Yes.
 20 Q And you and Dr. Muhl do a lot of work with
 21 them, with FEG?
 22 A We have some granted studies with them.
 23 Q And you've been studying their mesh for how
 24 many years? If we go back to '07, you've been doing
 25 their mesh for at least five years. Right? You've

3560

1 been working with them for the last five years. Right?
 2 A They have been employed for the first time in
 3 1994 to produce the Vypro with us, because Ethicon at
 4 that time, they needed someone from the Institute for
 5 Textile Engineering in Aachen. And so these guys, they
 6 give the structure of the Vypro at that time. And
 7 since then we are working on finding best solutions for
 8 meshes.
 9 Q I understand that and --
 10 A So I'm working since 1994 with these guys.
 11 Q So since '94 you've been working with FEG?
 12 A Yes.
 13 Q And you worked with Ethicon up until about,
 14 what, '05 as a consultant?
 15 A 2005.
 16 Q 2005. And then you were no longer a
 17 consultant for Ethicon. Correct?
 18 A Yes.
 19 Q But did you stay as a consultant for FEG
 20 after 2005?
 21 A Yeah. We had a lot of -- or several granted
 22 projects together.
 23 Q As we sit here today, you are a paid
 24 consultant for FEG. Correct?
 25 A Yes.

1 Q You talked about patents earlier. Do you
 2 remember that?
 3 A Yes.
 4 Q Those are mesh patents. Right?
 5 A Yes.
 6 Q Did you assign those patents to FEG?
 7 A I didn't get the content of the sentence?
 8 Q Did you assign those patents to FEG?
 9 A With the FEG. They were patents from the FEG
 10 where I was a contributor to this.
 11 Q So you invented meshes. Correct? Or
 12 helped to invent meshes. Correct?
 13 A Yes, yes.
 14 Q And then you got a patent on that mesh.
 15 Correct?
 16 A I was mentioned on this patent, yes.
 17 Q Because you helped to invent it. Correct?
 18 A Yes.
 19 Q And then FEG, did they buy the patent from
 20 you?
 21 A No.
 22 Q You gave them the patent?
 23 A No. They claimed this patent for these meshes,
 24 and they made --
 25 Q Listed your name?

3562

1 A And they listed my name as a contributor. This
 2 was a procedure not done by every company, I have to
 3 admit.
 4 Q And what year did you start as a paid
 5 consultant for FEG? Was it '94 or did they start
 6 paying you sometime after '94?
 7 A No. It was '98 maybe, '99.
 8 Q So the last 14, 15 years you've been
 9 working for them?
 10 A As I told you, together with Ethicon, we have
 11 been working with the FEG starting in 1994.
 12 Q But the Ethicon work stopped in '05.
 13 Right? Your Ethicon worked stopped in '05. Right?
 14 A Yes. And the Ethicon work with the FEG stopped I
 15 think in 1997, 1998.
 16 Q For example, if we go to the DynaMesh
 17 website, the FEG website, we're going to find a picture
 18 of you on the website. Right?
 19 A I haven't seen it myself, but --
 20 Q You haven't seen the picture of the
 21 newspaper interview with you on the website?
 22 A I know there has been a -- we got an award to
 23 make a grant for visible meshes, and there has been a
 24 report in the newspaper and maybe they placed it on the
 25 website, but I didn't control their website. But it

3563

1 was an excellent project.

2 Q So we got this testing going on. And I
3 looked in the article, and it's not that big of a deal,
4 but you didn't -- there's no mention in the article
5 that you're a paid consultant for FEG or for DynaMesh.
6 Right?

7 A That is right. Maybe. So I have to check
8 whether there is any acknowledgment to any others.

9 Q And, sir, let me hand you another study.
10 I'm sure you've probably seen it. It's an article
11 called "Comparison of a lightweight polypropylene mesh
12 Optilene LP."

13 And, sir, what I'm going to do up here,
14 just so you and I are on the same page, I'm going to
15 use the letters -- that's an E, it doesn't quite look
16 like it -- EP for effective porosity. That's what I
17 mean by EP.

18 A Yeah.

19 Q Okay. So Jamey, take down what you got on
20 the screen and let's put up, it's DLTB00863.

21 And here we see, sir, a comparison of a
22 lightweight polypropylene mesh Optilene LP, and they're
23 looking at another mesh made out of a different
24 material called PTFE. Correct?

25 A Yep.

3564

1 Q And this is published in 2012?

2 A Yes.

3 Q In the Archives of Surgery?

4 A Yes.

5 Q And what we've got here are a number of
6 individuals, a number of physicians from the Department
7 of Surgery and Center of Minimally Invasive Surgery.
8 Do you see that? It's down here at the bottom. Let's
9 scroll up. Right there.

10 See, Department of Surgery and Center for
11 Minimally Invasive Surgery; is that right? And these
12 are doctors in Berlin. Right?

13 A In Berlin, yeah.

14 Q So let's go back up to the abstract. And
15 we see the purpose of the study, they say on the first
16 sentence, "The use of a mesh with good biocompatibility
17 properties" --

18 Biocompatibility, that's what we talked
19 about earlier. Right?

20 A Yes.

21 Q -- "is of decisive importance for the
22 avoidance of recurrences and chronic pain in endoscopic
23 hernia repair surgery."

24 And then we go a little further down to
25 "Methods," and we see that, "20 domestic pigs were

3565

1 implanted with either a lightweight large pore
2 polypropylene mesh, in this case Optilene LP, or this
3 other medium weight PTFE mesh." Correct, sir?

4 A Yes.

5 Q And we see over on, I think it's two pages
6 over, Jamey, if you could, we see up in the top right,
7 we see, "HE staining."

8 And that's once you get -- what they do is
9 they put these meshes in pigs. Right?

10 A Yes.

11 Q And then they let the pigs live for a
12 certain number of days. Right?

13 A Yeah.

14 Q And then, in this case, it was 94 days?

15 A Yeah.

16 Q And then the pigs are sacrificed. Correct?

17 A Uh-huh.

18 Q And then they take the mesh out, and then
19 they look at the mesh under microscopes. Correct, sir?

20 A Yes.

21 Q And that's the sort of stuff you do? I
22 mean, you put meshes in animals and then later examine
23 them under microscopes. Correct?

24 A Yes.

25 Q So we're at page 285. And HE staining,

3566

1 what's that, sir? Is that where you're staining the
2 slide so you can see them better?

3 A Yes. It marks the -- some cell components, the
4 nucleus, and so you can see a little bit better the
5 collagens or the scar.

6 Q So it says here, "HE staining showed good
7 integration of both meshes with only minor inflammatory
8 reaction and no bridging scar tissue between the
9 filaments"; is that right?

10 A Yes.

11 Q Then if we flip over to -- let's go to the
12 conclusion, Jamey, at the end of the article.

13 First paragraph of that conclusion. It
14 says, "In our experimental examinations, Optilene LP
15 and INFINIT showed comparable biocompatibility in terms
16 of chronic inflammatory reaction. The good tissue
17 integration and biocompatibility coupled with the good
18 adhesion characteristics on the tissue make the
19 Optilene and the INFINIT meshes suitable for
20 implantation in hernia repair surgery."

21 Did I read that correctly?

22 A Yes.

23 Q You can take that down.
24 All right, sir.

25 Jamey, can you put back up Dr. Klinge's

1 2007 article? Put up that Table 1. Do you remember?
 2 It's PLT0346. There you go.
 3 So now we're going to move on. We're going
 4 to skip over Sofradim and we're going to go to TiMesh.
 5 All right?
 6 A Yeah.
 7 Q And, again, TiMesh had 0 percent effective
 8 porosity. Correct?
 9 A Uh-huh.
 10 Q Sir, I'm going to hand you an article
 11 called -- well, let me just hand you that.
 12 Sir, you're familiar with this article.
 13 Correct?
 14 A Yes.
 15 Q I'm sorry, you can take this one down,
 16 Jamey, the one that you've got up, and let's put up
 17 DLTB00864. All right?
 18 And, Doctor, that's the one you're holding
 19 in your hands. Correct?
 20 A Yes.
 21 Q And you're familiar with this article?
 22 This is an article that you are one of the authors on.
 23 Correct?
 24 A Yes.
 25 Q And if we come down here, go up, Jamey.

3568

1 Right there. That's good. Kind of in the middle of
 2 this sentence, over in the abstract it says, "In
 3 Sprague-Dawley rats, mesh samples were placed in a
 4 subcutaneous position. And then 56, 84 and 182 days
 5 after mesh implantation, three animals from each group
 6 were sacrificed for morphological observations."
 7 Right?
 8 A Yes.
 9 Q And that Sprague-Dawley rats are just a
 10 type of rat that you use in some of your experiments.
 11 Correct?
 12 A Yes.
 13 Q So in the prior study, we saw pigs. And in
 14 this study, we see rats. Correct?
 15 A Yes.
 16 Q So after getting the TiMesh implanted in
 17 them after 56, then 84 and then 182 days, the animals
 18 were sacrificed and you took the meshes out and you
 19 examined them under microscopes, like the guys did with
 20 the Optilene in the pigs. Right?
 21 A Yes.
 22 Q So let's go over, Jamey, to 864.4 and that
 23 paragraph beginning, "Overall."
 24 We see that, "Overall, both mesh materials
 25 showed a moderate foreign body reaction with a small

1 amount of connective tissue formation indicating a good
 2 biocompatibility"; is that right? Did I read that
 3 correctly?
 4 A Yes.
 5 Q Sir, I'm going to hand you another article,
 6 and this one -- Jamey, this one is DLTB00865.
 7 Sir, have you ever seen this article?
 8 A I've seen it.
 9 Q And the title on this one is "Randomized
 10 clinical trial of laparoscopic hernia repair comparing
 11 titanium-coated lightweight mesh and medium-weight
 12 composite mesh." Correct?
 13 A Yes.
 14 Q And this is dated 2012. Correct?
 15 A Yes.
 16 Q TiMesh, the reason it's got "Ti" in front
 17 of its name is because it's a got a little bit of
 18 titanium that covers the mesh. Correct?
 19 A Yeah.
 20 Q So let's go up, Jamey. Let's look at
 21 "Methods." "Randomized controlled single-center
 22 clinical trial was designed using the basic principle
 23 of one unit, one surgeon, one technique and two meshes,
 24 a lightweight titanium coated mesh," and this is
 25 TiMesh, sir, we'll see it later in the article, "and a

3570

1 medium-weight collagen-polyester composite mesh. The
 2 primary endpoints were pain and recurrence. The
 3 secondary endpoints were morbidity and patient
 4 outcomes."
 5 And, sir, unlike the two that we looked at
 6 earlier, this is actually in humans. Right?
 7 A Yes.
 8 Q This isn't an animal study. Correct?
 9 A Yes.
 10 Q And we see down here over on the
 11 "Conclusions," and let's just block that paragraph on
 12 the "Conclusions."
 13 "The lightweight titanium covered
 14 polypropylene mesh was associated with less
 15 postoperative pain in the short term, lower analgesic
 16 consumption and a quicker return to everyday activities
 17 than the Parietex composite medium-weight mesh."
 18 And the recurrence rates at two years were
 19 no different; is that right? Did I read that
 20 correctly?
 21 A You read it correctly.
 22 Q Then the next page -- you can take that
 23 down. Jamey, the next page -- put that same article
 24 back up. Let's just go to the second page, near the
 25 bottom.

1 And we can see here, sir, that that's the
 2 TiMesh light that they were looking at. Right?
 3 All right. You can take that down.
 4 Sir, I think I've already handed you this
 5 article, but I've got another copy if you need it.
 6 This is Defendant's Exhibit DLTB00266. We've already
 7 referred to that once before, but feel free to use this
 8 document.
 9 And the jury has already seen this document
 10 or this article. This is your article. Correct, sir?
 11 A Yes.
 12 Q So let's go over to 266.11. And under
 13 "TiMesh light and extra light," we read down here, this
 14 is where you're talking about TiMesh light. Correct,
 15 sir? And TiMesh extra light?
 16 A Yes.
 17 Q And "Both" -- it says here, "Both mesh
 18 modifications were announced as a revolution on the
 19 mesh market and have the best biocompatibility
 20 possible. Indeed, the titanium modified meshes exhibit
 21 a significantly increased biocompatibility compared
 22 with conventional heavyweight small porous meshes."
 23 Correct? Did I read that right?
 24 A Yes.
 25 Q Sir, we're now going to move to Gynemesh

3572

1 and Prolift, which you tested not in 2007 but in 2012.
 2 Correct?
 3 A Yeah.
 4 Q Sir, I'm going to hand you Defendant's
 5 Exhibit 2257.46. Sir, I've only got one copy, so I'm
 6 going to let you look at it, then I might take it back
 7 from you for just a second.
 8 A That's fine.
 9 Q Just take a look at that.
 10 After you've had a chance, is that one of
 11 the documents that you were sent?
 12 A Yeah, I have seen it.
 13 Q That's an Ethicon document; is that right?
 14 A Yes.
 15 Q And, sir, I've got a sticky there.
 16 Do you see the sticky on that page?
 17 A Sticky?
 18 Q Yeah. That's what we got up on the screen.
 19 Right?
 20 A Yeah, yeah.
 21 Q And it says here, "Pore size of Gynecare
 22 Gynemesh PS"; is that correct?
 23 A Yeah.
 24 Q And then down here we've got 2530, and
 25 that's kind of a funky looking UM. Right?

1 A Yes.
 2 Q And in scientific language, is that the
 3 symbol for microns?
 4 A Yes.
 5 Q So if you -- as I understand this, what
 6 this is saying is that the distance from this spot
 7 right here running through this spot right here is
 8 2,530 microns. Correct?
 9 A That's what it says, yep.
 10 Q I'm sorry?
 11 A Yeah.
 12 Q Remember we talked earlier about how to
 13 compare millimeters to microns, we said that 1,000
 14 microns is equal to 1 millimeter. Correct?
 15 A Yes.
 16 Q So if assuming the math and the
 17 measurements here are correct, the distance from this
 18 spot right here to this spot right here would be
 19 2,530 microns. Correct?
 20 A That is correct.
 21 Q And on this -- and then up here -- this is
 22 the width, and I guess they call that the height.
 23 Correct?
 24 A You can call it --
 25 Q You can call it whatever you want to call

3574

1 it, but at least the distance here is 1,750 microns.
 2 Correct?
 3 A Yes.
 4 Q And then here it says, "Macroporous."
 5 I think you talked earlier about
 6 microporous and macroporous. Correct?
 7 A Yes.
 8 Q And microporous means the mesh has a small
 9 pore; is that correct? I know that you can get --
 10 A You can use this expression if you made a
 11 reference that this is the definition of Amid from
 12 1997, and then this is the type of macroporous.
 13 Q So under the Amid classification that
 14 you talked about, which was I guess Dr. Amid; is that
 15 right?
 16 A Prof. Amid. Prof. Amid.
 17 Q He created a classification of meshes and
 18 published on it back in 1997; is that right?
 19 A In the first issue of Hernia, yes.
 20 Q In the first issue of Hernia.
 21 And under his definition, this would be --
 22 the Gynecare Gynemesh PS would be defined as
 23 macroporous because it had pores at least 75 microns.
 24 Right?
 25 A Yes.

3575

1 Q You can take that down.
 2 Sir, I'm handing you what's been marked as
 3 DLTB00104.
 4 And, sir, you know this article because you
 5 wrote it. Correct?
 6 A Yes.
 7 Q And this is published in Hernia in 2004.
 8 Correct?
 9 A Yes.
 10 Q And the title is "Polypropylene in the
 11 intra-abdominal position: Influence of pore size and
 12 surface area." Correct?
 13 A Yes.
 14 Q Jamey, let's go to the next page, 104.2.
 15 And here, sir, under number 2, we see
 16 "Group II." Correct?
 17 A Yes.
 18 Q In other words, I think what was going on
 19 here, sir, is you were looking at several different
 20 polypropylene meshes. Correct?
 21 A That is correct.
 22 Q That's what you were doing in this study?
 23 A Very, very huge lot of pores. We wanted to have
 24 this polypropylene and to look what happens within the
 25 abdominal cavity at this.

3576

1 Q So you looked at -- three different
 2 polypropylene meshes are investigated. Correct?
 3 A Yes.
 4 Q And they all differed in weight, filaments
 5 and pore size. Correct?
 6 A Yes.
 7 Q And there's Group I, and they were small
 8 porous with pore sizes of .6 millimeter.
 9 And if it's .6 millimeter, that would be
 10 600 microns. Correct?
 11 A Yes.
 12 Q Heavyweight mesh for monofilament
 13 polypropylene. And then we go to Group II. And it's
 14 PP 2.5.
 15 And that means the medium porous, the pore
 16 size is 2.5 millimeters. Correct?
 17 A Yes. However --
 18 Q That's what you've got written up there, I
 19 should say?
 20 A Yeah. But this is misleading, so -- it is for
 21 surgeons.
 22 Q And, sir, I'm just simply asking you what
 23 the words on the paper say.
 24 A Yes.
 25 Q And let's go over to the next page. And

3577

1 we've got pictures of a number of the meshes that
 2 you're looking at. Right?
 3 A Yes.
 4 Q And you got one here that's 2.5. Correct?
 5 A Yes.
 6 Q And where's that PowerPoint?
 7 It looks a whole lot like that Gynemesh
 8 PowerPoint?
 9 A Yes.
 10 Q Now, were you testing Gynemesh?
 11 A Gynemesh?
 12 Q Were you testing Gynemesh here?
 13 A Gynemesh?
 14 Q Yes.
 15 A Gynemesh.
 16 Q Or Prolene Soft?
 17 A Yeah. As I said in the deposition, I cannot be
 18 sure. There is -- there are a lot of similarities.
 19 Whether this was exactly coming out of the product or
 20 whether it was specifically done, I cannot state. But
 21 it looks quite similar, so from this appearance, there
 22 seems not to be a difference.
 23 Q And in this article, you were the author.
 24 Correct?
 25 A Yes.

3578

1 Q And you wrote down 2.5, didn't you?
 2 A Yeah.
 3 Q Jamey, let's go to 104.6. Same article.
 4 And let's go down here toward the bottom.
 5 And it says, "Polypropylene has been used
 6 in hernia surgery for almost five decades. Compared to
 7 other biomaterials, it shows a high biocompatibility,
 8 with no degradation but a good integration into the
 9 neighboring tissue." Correct?
 10 A Yes.
 11 Q And then, Jamey, let's take that one down.
 12 We'll go to the next one. Sir, this is
 13 Defendant's Exhibit DLTB00259.
 14 You're familiar with this one? This is
 15 another article that you wrote, sir. Correct?
 16 A Yes.
 17 Q This is in 2001. Correct?
 18 A Yes.
 19 Q And the title of it is "Functional and
 20 morphological evaluation of a low-weight, monofilament
 21 polypropylene mesh for hernia repair." Correct?
 22 A Yes.
 23 Q And let's go into the abstract, about two
 24 or three sentences down, beginning with "In the present
 25 study."

1 And, sir, in the abstract you often
 2 describe what it is you're doing so that the readers
 3 don't have to go through the entire article to
 4 understand what you're doing. Right?
 5 A Yes.
 6 Q "So in the present study, a low-weight
 7 polypropylene mesh (LW)" --
 8 And I assume by that you just mean low
 9 weight. Correct?
 10 A Yeah.
 11 Q -- "made purely of monofilaments was
 12 compared to a common heavy-weight polypropylene mesh
 13 (HW) in regard to the functional consequences and the
 14 tissue response."
 15 And then, sir, you go on to indicate that
 16 you -- again, you were implanting mesh in rats, and you
 17 were letting them go anywhere from three to 90 days,
 18 and then you were sacrificing the rats and then you
 19 were looking at the mesh after the tissue had grown
 20 into it under microscopes and the other instruments
 21 that you use. Correct?
 22 A Yeah.
 23 Q And if we go down to the bottom of this
 24 page, we actually see right there at the bottom that
 25 Ethicon was one of the grant sponsors for this study of

3580

1 yours. Correct?
 2 A That is correct. They did -- they got a report
 3 of it.
 4 Q According to the study, sir, you had -- 90
 5 male rats were studied. Does that sound right?
 6 A Yeah.
 7 Q Let's go to the table on page 131, up
 8 toward -- I'm sorry, it's actually 259.3.
 9 Sir, these are the textile characteristics
 10 of the two meshes that you were testing. Correct?
 11 A Yes.
 12 Q And you called it here a heavyweight, HW
 13 and low weight, low W, and I want to kind of focus in
 14 on the LW.
 15 Now, it says 45 grams. Correct?
 16 A Yep.
 17 Q That's basically Gynemesh.
 18 A Yep.
 19 Q Right? It's 45 grams?
 20 A Quite similar, yeah.
 21 Q And the pore sizes here you indicate are
 22 greater than 1 millimeter. Correct? Or greater than
 23 1,000 -- well, here you use millimeters. Right?
 24 A Yes.
 25 Q Pore sizes greater than 1 millimeter.

1 Correct?
 2 A Yep. That's in the table.
 3 Q And then let's go to the conclusion or
 4 toward the end on 259.7.
 5 And, sir, part of what you were looking at
 6 here was you were looking at a heavyweight mesh and a
 7 lightweight mesh and you were asking yourself or you
 8 guys were studying the question whether it's better to
 9 have a low weight mesh than a heavyweight mesh in terms
 10 of complications. Right?
 11 A Yeah.
 12 Q And when we go here to the end near the
 13 bottom where it begins, "Therefore." It's kind of
 14 where you're summing up your conclusions. And it says,
 15 "Therefore, a reduction of the mesh material, and of
 16 the foreign body surface, in particular, to the lowest
 17 extent possible is recommended. The present study
 18 shows for the first time that this aim can be achieved
 19 by the exclusive use of nonabsorbable polypropylene
 20 monofilaments."
 21 Did I read that correctly?
 22 A Yes.
 23 Q Sir, I'm handing you Defendant's Exhibit
 24 DLTB00150.
 25 Have you seen this before, sir?

3582

1 A No, I cannot recall it.
 2 Q Sir, the title of this article is
 3 "Histological inflammatory response to transvaginal
 4 polypropylene mesh for pelvic reconstructive surgery."
 5 Correct?
 6 A Yep.
 7 Q All right. And if we look down at the
 8 bottom, we see it's published in the Journal of Urology
 9 in 2009. Correct?
 10 A Yep.
 11 Q And I don't know if we've covered the
 12 Journal of Urology, but that's not a journal that you
 13 subscribe to. Correct, sir?
 14 A Not for our department. For the university as
 15 well, it is possible, of course.
 16 Q But I don't think -- but you personally
 17 don't have a subscription, you don't get this mailed to
 18 your home, the journal of urogynecology -- I mean, I'm
 19 sorry, the Journal of Urology, do you?
 20 A No, I don't get it at home.
 21 Q And we see that it's authored by -- we've
 22 got Carolyn Elmer, Bo Blomgren, Christian Falconer,
 23 Anju Zhang and Daniel Altman. Correct?
 24 A Yes.
 25 Q You've got five authors. And it says from

1 the "Division of Surgery and Urology, Department of
 2 Obstetrics and Gynecology, Department of Clinical
 3 Sciences" and "Sweden." Correct?
 4 A That is correct.
 5 Q So these are gynecologists who are writing
 6 on this issue of inflammatory response to transvaginal
 7 polypropylene mesh. Correct?
 8 A Yes, that's correct.
 9 Q And in the purpose it says, "We
 10 prospectively evaluated the histological inflammatory
 11 response to the large polypropylene transvaginal mesh
 12 used for pelvic organ prolapse surgery."
 13 Did I read that right?
 14 A Yes.
 15 Q Then we go down to "Materials and Methods."
 16 "Ten patients and 8 controls underwent vaginal punch
 17 biopsy sampling before surgery and patients also
 18 underwent it one year after pelvic reconstructive
 19 surgery using polypropylene mesh. Foreign body
 20 response to the mesh was assessed using a combination
 21 of histological, semiquantitative and computerized
 22 image-based analysis." Correct?
 23 A Yes.
 24 Q And so just to break that down just a
 25 little bit, when we talk about ten patients, we're

1 some tissue using the biopsy before they underwent the
 2 surgery, and then a year later, another piece of tissue
 3 is biopsied out of the same women. Right?
 4 A Yeah.
 5 Q Let's go over to Defendant's Literature
 6 150.2. Let's go up under "Materials and Methods,"
 7 second sentence. It says, "Ten consecutive patients
 8 undergoing pelvic organ prolapse surgery using the
 9 Prolift system and eight controls undergoing elective
 10 gynecological surgery for other benign indications were
 11 included in the study." Right?
 12 A Yes.
 13 Q So these ten women actually had Prolifts in
 14 them. Correct?
 15 A Yep.
 16 Q And let's flip over to 150.6. And they
 17 tell us here after taking us through all the different
 18 mathematical values that they calculate in all their
 19 examinations, they tell us that "The combined results
 20 of the clinical and histological inflammatory
 21 evaluation suggest that biocompatibility was
 22 satisfactory."
 23 Did I read that correctly?
 24 A You read this correctly.
 25 Q Jamey, if you could put back up Dr.

1 talking about ten patients who have actually had the
 2 polypropylene transvaginal mesh implanted inside their
 3 bodies. Correct?
 4 A Yes.
 5 Q And when we talk about eight controls, are
 6 we talking about women who have not had the mesh
 7 implanted inside their bodies?
 8 A I guess it is just like this, yeah.
 9 Q So when we talk about they underwent
 10 vaginal punch biopsy sampling, do you know what that
 11 is?
 12 A I don't know exactly how they did it, how deep
 13 and --
 14 Q Do you know what it is?
 15 A Yeah. I can imagine.
 16 Q So vaginal punch biopsy sampling is where
 17 the doctors actually go into the woman, and they take a
 18 biopsy or they pinch out a piece of the woman's own
 19 tissue in that area. Correct?
 20 A Yes.
 21 Q And they did it before surgery and then
 22 they had it done one year after pelvic reconstructive
 23 surgery using the mesh. Correct?
 24 A Yes.
 25 Q So they pulled out some skin -- I'm sorry,

1 Klinge's article, Dr. Muhl and Dr. Klinge's article,
 2 DLTB360.
 3 Sir, so we could -- just so I fill the
 4 chart out, what did we have for effective porosity over
 5 here on Gynemesh/Prolift? 26 percent at rest, 0
 6 percent at strain?
 7 A At strain, 0. And without strain, 26 percent.
 8 Q So we'll go with the lower number.
 9 So we're back here kind of where we
 10 started. And, again, sir, I don't want to dwell on the
 11 points that we've already discussed with Dr. Muhl, but
 12 when you tested the Prolift in 2012, you didn't test
 13 the mesh with human tissue incorporated into it.
 14 Correct?
 15 A That is correct.
 16 Q Let's go to this article at .7, 360.7.
 17 And just to reorient, the procedure that
 18 you outlined in this article is the procedure that you
 19 used to test the Prolift and the Gynemesh. Correct?
 20 A Yes.
 21 Q So let's highlight that first sentence
 22 there, right above the "Conclusion."
 23 "Though the present technique offers a
 24 reproducible way to objectify the porosity of flat
 25 textile structures, it is limited to a two-dimensional

3587

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1 analysis."
 2 Did I read that correctly?
 3 A Yes.
 4 Q And then let's go down to the last sentence
 5 in that paragraph, "Furthermore, examination of
 6 porosity after tissue incorporation can be measured
 7 only if the tissue is completely removed and the
 8 textile is kept perfectly flat."
 9 Did I read that correctly?
 10 A Yeah.
 11 Q And now let's go to the first page of the
 12 article, point 1 in the abstract, last sentence.
 13 And you told us, sir, when you came up with
 14 this protocol in 2007 that "Further in vivo studies" --
 15 And those are studies inside the human
 16 body. Right?
 17 A Yes.
 18 Q "Further in vivo studies have to
 19 investigate whether the preservation of a high
 20 effective porosity under stress may help to improve
 21 biocompatibility of textile implants."
 22 Did I read that correctly?
 23 A Yes.
 24 Q And, sir, let's move to 360.3 in the
 25 article, toward the bottom under "Porosity

3588

1 determination."
 2 Sir, you told us there in your article in
 3 2007 that pore sizes that prevent any bridging effect
 4 but permit ingrowth of physiological tissue should
 5 exceed a distance of 1,000 microns, that's that 1
 6 millimeter we've been talking about, between two
 7 polypropylene filaments. Correct?
 8 A Yes.
 9 Q So, sir, you also told us later on in this
 10 article, page 360.5, right in the middle, "Pore sizes
 11 of greater than 500 to 600 microns permit ingrowth of
 12 soft tissue, and pore sizes of greater than 200 to 300
 13 favor neovascularization." Right?
 14 A Yes.
 15 Q The ingrowth of blood vessels. Right?
 16 A Neovascularization is the ingrowth of blood
 17 vessels and of soft tissue with scar. Scar and soft
 18 tissue as well.
 19 Q When you tested the Prolift in 2012, you
 20 tested it at 1,000 microns. Right? In other words,
 21 when you tested the effective porosity, you used 1,000
 22 microns?
 23 A 1,000 microns, yes.
 24 Q That's 1 millimeter?
 25 A Yes.

1 Q You did not use 500 to 600 microns.
 2 Correct? You used 1,000?
 3 A Yes. Because we wanted to have the scar.
 4 Q Now, sir, we're rounding the corner here.
 5 I've handed you Defendant's Exhibit DLTB00026.
 6 By the way, sir, when you tested the
 7 Prolift in 2012, you tested the Prolift using 1,000
 8 microns, and you tested the DynaMesh at 600 microns.
 9 Correct?
 10 A Because it's a PVDF, it's another material.
 11 Q So 1,000 for one and 600 for the other.
 12 Right?
 13 A Yeah.
 14 Q Now, sir, I've handed you an article called
 15 "Classification of biomaterials and their related
 16 complications in abdominal wall hernia surgery."
 17 And let's go up to the very top.
 18 Sir, I think you told us this was the very
 19 first edition of Hernia. Right?
 20 A I guess, yeah, it was number one.
 21 Q Yeah, this was number one.
 22 A Yeah.
 23 Q And Hernia is -- I mean, it's a big
 24 deal in -- it's a big deal for hernia surgeons. I
 25 mean, it's not light reading for the rest of us, but

3590

1 hernia surgeons, this is a big article, I mean, it's a
 2 big publication, Hernia? Let me phrase -- no, no. Let
 3 me phrase it another way.
 4 It's an important journal to hernia
 5 surgeons?
 6 A Meanwhile, yeah. They started there.
 7 Q So let's scroll up a little bit.
 8 And this is authored by Prof. Amid.
 9 Correct?
 10 A Yes.
 11 Q And you talked about Prof. Amid earlier
 12 today. Correct?
 13 A Yes.
 14 Q Let's scroll up just a little bit more.
 15 And what Prof. Amid was concerned with in
 16 this article was classifying biomaterials, i.e., meshes
 17 among other things, and their related complications in
 18 abdominal wall hernia surgery. Correct?
 19 A That is correct.
 20 Q So we see down here for type I, "Type I are
 21 totally macroporous prostheses" --
 22 And macroporous, we talked about that
 23 earlier, those are the large pore fabrics. Correct?
 24 A You have to decide what is large pore.
 25 Q Let me give it to you a different way.

1 Macroporous meshes have larger pores than
 2 microporous meshes?
 3 A That is okay.
 4 Q There we go.
 5 Totally macroporous prostheses, and that's
 6 prostheses is just another word for --
 7 A Mesh.
 8 Q -- mesh. Right?
 9 A Yes. So we all know.
 10 Q Such as Atrium, Marlex, Prolene and Trelex.
 11 And I think Atrium, Marlex and Prolene were
 12 ones you put in some of your patients. Right?
 13 A Yes.
 14 Q "These prostheses contain pores larger than
 15 75 microns." Correct?
 16 A Yes.
 17 Q When we talk about 75 microns, I had to
 18 struggle with this, that's why I keep repeating myself,
 19 pore sizes that are greater of 1 millimeter, that's
 20 1,000 microns. Right?
 21 A Yes.
 22 Q So when we talk about 75 microns, we're
 23 talking about something that's less than 10 percent of
 24 that 1 millimeter. Correct? 75 microns --
 25 A Yes.

3592

1 Q "These prostheses contain pores larger than
 2 750 microns, which is the required pore size for
 3 admission of macrophages." Correct?
 4 A Yep.
 5 Q "Fibroblasts"?
 6 A Yep.
 7 Q "Fibroplasia, blood vessels, angiogenesis
 8 and collagen fibers into the pores." And then it says,
 9 "Boby, et al., 1982."
 10 And that would be an article published by
 11 Bobyn in 1982. That's what it's talking about there.
 12 Right?
 13 A You're right.
 14 Q And then White in 1988. Correct? That's
 15 another article?
 16 A Yep.
 17 Q And then White, et al. in 1981. Correct?
 18 A Yes.
 19 Q And then, sir, handing you DLTB00139,
 20 "Synthetic and biodegradable prostheses in pelvic floor
 21 surgery."
 22 You've seen this article, certainly, sir,
 23 haven't you, sir?
 24 A Yes.
 25 Q And this is the Deprest article. Correct?

1 Or at least I refer to it as Deprest, because the first
 2 author is Deprest. Correct?
 3 A Yes.
 4 Q And as you can see right here, "Center for
 5 Surgical Technologies, Faculty of Medicine, Department
 6 of Obstetrics and Gynecology" in Belgium. Correct?
 7 A Yes.
 8 Q And so these are pelvic floor surgeons --
 9 A Yes.
 10 Q -- in Belgium discussing synthetic and
 11 biodegradable prostheses in pelvic floor surgery.
 12 Correct?
 13 A Yes.
 14 Q We've got one, and I think one of them
 15 might be a pathologist, but a pathologist is still --
 16 they're still a doctor, aren't they? At least over
 17 here in the United States they're a medical doctor.
 18 Are pathologists in Belgium also a medical doctor?
 19 A I would guess. I'm not certain, but I guess.
 20 Q We've got one, two, three, four, five, six,
 21 seven, eight, nine medical doctors. Correct?
 22 A I cannot control it for everyone, but I guess.
 23 Q And we're talking 2005. Right? That's the
 24 year Prolift comes on the market. Right?
 25 A Yes.

3594

1 Q And let's go to page 139.4, last sentence.
 2 "And these pelvic floor surgeons tell us pore sizes of
 3 greater than 75 microns allow for rapid ingrowth of
 4 fibroblasts and vascular elements necessary to anchor
 5 the implant within the native tissue."
 6 Did I read that correctly?
 7 A You read this correctly.
 8 Q And then, sir, and I promise you we're
 9 getting close to the end here, I'm handing you another
 10 article. The one I just showed you -- the one up on
 11 the board is 2005. Now we're going to 2006, one year
 12 later. Jamey, let's put up DLTB00140.
 13 And here we see Deprest again. Correct?
 14 A Yes.
 15 Q And, sir, we see Deprest, Fang Zheng, et
 16 cetera. We see -- these are a number of physicians.
 17 And I compared -- so Deprest has basically got an
 18 article in 2005 and an article in 2006. Correct?
 19 A Yes.
 20 Q And I compared the authors of the two, and
 21 there's some overlap, but I think, what did we count,
 22 nine on the first one and then I think there are a
 23 couple more over here on the 2006 article that are not
 24 also co-authors on the 2005 article. I mean, I may
 25 have my numbers off, but I think it's somewhere around

1 11 total medical doctors between the two articles,
 2 maybe 12. Okay?
 3 And we see, sir -- Jamey, why don't you
 4 take down the one on the left. There you go.
 5 "The biology behind fascial defects and the
 6 use of implants in pelvic organ prolapse repair."
 7 Correct? Correct, sir?
 8 A Yes.
 9 Q And then let's go to page 140.3. And kind
 10 of go toward the bottom. Pick up right there with that
 11 sentence beginning with "Pore."
 12 It says, "Pore size is also an important
 13 factor for fibroblast infiltration, flexibility and
 14 mechanical integration. Pore sizes of greater than
 15 75 microns allow for rapid ingrowth of fibroblasts and
 16 vascular elements necessary to anchor the implant
 17 within the native tissue."
 18 Did I read that correctly?
 19 A Yes, you read it correct.
 20 Q Sir, Defendant's Exhibit DLTB00261. The
 21 title of this article is, "Modified classification of
 22 surgical meshes for hernia repair based on the analyses
 23 of 1,000 explanted meshes." Correct?
 24 A Yes.
 25 Q And the lead author is Dr. Klinge.

3596

1 Correct?
 2 A Yes.
 3 Q And it's published -- it was accepted April
 4 2012 and it was published in May of 2012. Correct?
 5 A Yep.
 6 Q Sir, if you would, look with me, page
 7 261.6. That paragraph there, Jamey, that begins
 8 "Furthermore," about halfway down.
 9 It says, "However" -- and these are your
 10 words. Correct, Dr. Klinge?
 11 A What?
 12 Q These are your words?
 13 A Yeah.
 14 Q "However, it is still open for further
 15 studies whether 500 microns is a reliable limit for
 16 histology and 1,000 microns for the calculation of the
 17 effective porosity or whether this should be modified."
 18 A Yes.
 19 Q Did I read that right?
 20 A Correct.
 21 Q "Though a standardized measurement of the
 22 effective porosity that considers only large pores with
 23 sufficient geometry to avoid bridging may best provide
 24 a qualitative criterion to differentiate these two
 25 groups, it may be speculated" --

1 A Yes.
 2 Q -- "whether the assumption of a best pore
 3 size of 1,000 microns for preserving an effective
 4 porosity has to be adjusted." Correct?
 5 A That is correct.
 6 MR. GAGE: Nothing further, Your Honor.
 7 - - -
 8 REDIRECT EXAMINATION
 9 - - -
 10 BY MR. ANDERSON:
 11 Q Dr. Klinge, let's actually start right
 12 where he ended off.
 13 This 1,000 explant classification, what was
 14 the purpose of this being done in Europe for hernia --
 15 for a hernia registry? Explain that hernia registry.
 16 A From the European Hernia Society, we were asked
 17 to build up a registry to get better information, what
 18 is the outcome of the patients after hernia repair. We
 19 all have learned that clinical studies usually have
 20 strict limitations, and, therefore, it was -- the task
 21 was to build up an international registry. And for
 22 this registry, we need some information. We want to
 23 put in which material has been used. Meanwhile, more
 24 than 220 different mesh materials are used by hernia
 25 surgeons. And if you place just a name in this

3598

1 registry, it will be hardly possible to get any
 2 feedback what is the impact of the clinical outcome.
 3 And, therefore, we want to have a grouping of these
 4 mesh materials so that we can make a better
 5 interpretation of these data.
 6 And there, in this field, we categorized
 7 two different groups, the so-called small pore meshes
 8 and the large pore meshes. And we made it in
 9 cooperation with all major manufacturers in Germany,
 10 because they wanted to have a classification or a
 11 grouping as well.
 12 Q Let me stop you right there.
 13 And one of those manufacturers was Ethicon.
 14 Correct?
 15 A Yes.
 16 Q And as part of this regrouping and
 17 reclassification of hernia meshes, your work regarding
 18 1,000 microns was listed as one of the ways to classify
 19 the meshes that come into this registry in Europe.
 20 Correct?
 21 A Yes.
 22 Q And so Ethicon signed off on the registry
 23 and the manner in which you set it up for the European
 24 Hernia Society. Correct?
 25 A They agreed to this grouping.

1 Q Also listed within this article that was
2 just shown to you about the 1,000 explants, this is
3 actually the testing that you and Muhl have done and
4 that the jury has seen. Correct?

5 A Yes.

6 Q Showing how you can measure effective
7 porosity by looking at these 1,000-micron pores.
8 Correct?

9 A Yes.

10 Q And the importance of having these
11 1,000-micron pores is also listed in this article,
12 isn't it?

13 A Yeah. We applied this grouping then to these
14 1,000 explants. And it is clearly -- can clearly be
15 seen that the mound of inflammation and connective
16 tissue means scar formation is higher in the small pore
17 group meshes than in the large pore group meshes. And,
18 therefore, if we want to have a grouping that predicts
19 a little bit the outcome, we feel comfortable to focus
20 on these pore sizes.

21 Q And Ethicon is a signatory, they signed off
22 as one of the manufacturers agreeing to this
23 classification and this grouping of meshes in the
24 registry. Correct?

25 A They agreed to this.

1 to say, great job on this reclassification after he's
2 opened the door. Absolutely relevant.

3 I was going to read the first two
4 paragraphs -- actually, just the first line of the
5 second paragraph. First paragraph and the first line
6 of the second.

7 MR. GAGE: And, Your Honor, you understand
8 my objection.

9 THE COURT: The objection is sustained.
10 It's hearsay.

11 - - -

12 (The sidebar ended.)

13 - - -

14 BY MR. ANDERSON:

15 Q Just so the jury understands, this 1,000
16 explant study, how many years of explants -- and by
17 explants, we're talking about tissue that has been
18 taken out of hernia surgery and has been evaluated
19 histopathologically by you and Dr. Klosterhalfen.
20 Correct?

21 A That's correct. We started to collect these
22 materials soon after 2000.

23 Q And you published this in 2012. Correct?

24 A This evaluation of these 1,000. But in between,
25 we have preliminary reports of a group of them.

1 Q Put up Plaintiff's 0689 if you would,
2 please, PLT0689.

3 MR. GAGE: Your Honor, may we approach?

4 - - -

5 (The following occurred at sidebar:)

6 MR. GAGE: Your Honor, this is a letter to
7 the editor, and --

8 THE COURT: I usually -- in these cases, I
9 haven't allowed letters to the editor.

10 MR. ANDERSON: I purposely did not bring up
11 the 1,000 explants because I didn't want to go here.
12 He raised it and he put it up as the last exhibit. And
13 so I wanted to show that their colleagues have thanked
14 them for doing this important work.

15 MR. GAGE: Your Honor, just for the record,
16 my objection is that it's hearsay because it's a letter
17 to the editor and it's not peer reviewed and it doesn't
18 come within any of the exceptions to the hearsay rule.

19 MR. ANDERSON: And it's the Hernia journal
20 that he just had this witness say is a very important
21 journal over there. So from the Hernia journal, which
22 he had him establish was so important, here we have
23 commenters, these are authors from the work that he's
24 been showing him for the last two-and-a-half hours,
25 Kockerling and Jacob, and they write in to the Hernia

1 Q So 12 years of 1,000 explants that came
2 from human beings that you actually looked at, and you
3 looked at various factors on those. Correct?

4 A Yes.

5 Q And pore size was one of them. Correct?

6 A Pore size was one of it, proliferation and
7 collagen deposition and...

8 Q And after looking at 1,000 explants, did it
9 confirm your findings that once the fibers in these
10 explants were greater than 1 millimeter but --

11 MR. GAGE: Objection, leading.

12 MR. ANDERSON: I'll withdraw it.

13 BY MR. ANDERSON:

14 Q Did this paper confirm any of your
15 findings, earlier findings, regarding 1 millimeter is
16 required for fatty tissue ingrowth?

17 A It is clear that the larger pores are -- have
18 advantages in regards to their partial volume of
19 inflammatory tissue and of connective tissue.

20 Q So --

21 A That can be shown by this.

22 Q So the 1,000 explants, did that confirm or
23 refute your -- did that confirm 1,000 microns was
24 necessary for fatty tissue ingrowth?

25 A Yeah. Our look at all these explants confirmed

1 this as a critical cutoff.

2 Q And was there ever a statement by Prof.
3 Amid in response to this reclassification of hernia
4 meshes?

5 MR. GAGE: Objection.

6 THE WITNESS: When he got aware of this, he
7 sent an e-mail with a congratulations.

8 MR. GAGE: Objection, Your Honor.

9 THE COURT: The objection is sustained as
10 to what Dr. Amid's response was. It was a hearsay
11 e-mail as opposed to something the doctor published.

12 MR. ANDERSON: That's fine.

13 BY MR. ANDERSON:

14 Q You were just shown an article by Jan
15 Deprest. And what was read to you is, "Pore size is
16 also an important factor for fibroblast infiltration,
17 flexibility and mechanical integration."

18 Now, I want to clear this up, because there
19 was 75 microns, 1,000 microns and 1 millimeter. And I
20 want to clear this up for the jury, if we could,
21 please.

22 What happens --

23 MR. ANDERSON: Do you mind if I use your
24 paper?

25 MR. GAGE: No.

1 MR. ANDERSON: Thank you.

2 BY MR. ANDERSON:

3 Q What happens -- what types of cells can go
4 into a small pore that has 75 microns?

5 A So most of the local cells, inflammatory cells,
6 are in a range of 5 to 7 microns. So you can choose
7 whether -- yeah. 5 -- 15 of these cells can go
8 parallel into these microns.

9 Q So if the mesh has holes that are only
10 75 microns, can any new tissue ingrowth occur?

11 A It depends what is the definition of a tissue.

12 Q Thank you.

13 What type of tissue can grow in at
14 75 microns?

15 A You always will find that there are some
16 macrophages in combination with some fibroblasts. No
17 one will object to this.

18 Q Fibroblasts meaning scarring?

19 A Scarring.

20 Q So at 75 microns in the pore, we still have
21 scar. Correct?

22 A Yes.

23 Q Then the next thing he read to you was,
24 "Peak ingrowth is reached at pore size around 400 to
25 500 microns." Correct?

1 A Yeah.

2 Q What can grow into the pore at 400 to
3 500 microns? What type of cells, if that is laying in
4 a human tissue, and these are the size of the mesh
5 hole?

6 A This limit usually is taken -- if you have some
7 tissue ingrowth, you need some vessels for providing
8 the blood supply in it. And it was generally accepted
9 that you need a pore size of this diameter so that
10 pore -- that vessels are growing in and providing these
11 cells with blood. If the pores are smaller, you don't
12 have this ingrowth of the vessels. So this is a cutoff
13 for -- that you see ingrowth of vessels.

14 Q So you can get some vessels?

15 A Yes.

16 Q Will you get new fatty tissue ingrowth that
17 we want for the implant to remain flexible?

18 A No. We didn't see it -- we didn't saw it in
19 these small pores.

20 Q And you called fat tissue good tissue.
21 Correct?

22 A Fat tissue is good tissue, because it means that
23 it is -- yeah. It is not replaced by scar tissue.

24 Q So at 75 microns, you can get a few
25 macrophages, and that's just our body's white blood

1 cells, to eat some tiny bacteria. Correct?

2 A Macrophages, few fibroblasts, so -- but there is
3 only room for 10, 15 cells in a row.

4 Q Correct. So when the hole gets bigger to
5 400 to 500 microns, you can get some vessels, but no
6 fat. I don't write as good as Will.

7 No fat, still no good tissue. Correct?

8 A We don't see any fat there.

9 Q Then what wasn't read to you from this
10 article, I would like to, which says, after the
11 sentence, "Peak ingrowth is reached at pore size around
12 400 to 500 microns."

13 And that would be ingrowth of scar tissue.
14 Correct? Ingrowth of scar tissue?

15 A Yep.

16 Q Right. So when they're talking tissue
17 ingrowth, they're not talking good tissue ingrowth,
18 they're talking bad tissue ingrowth. Correct?

19 A They don't differentiate it.

20 Q Right. So then larger pores -- after that
21 it says, "Larger pores limit the fibrosis process to
22 the perifilament region."

23 That was those pictures we saw with the
24 little dots around the side. Correct?

25 A That is --

3607

3609

1 Q And if they were far enough away, we would
2 have a good fat in it, but if we had these three
3 together, like we saw in multiple things, it would get
4 a scar plate. Correct?

5 A So they are absolutely in line with our
6 conception.

7 Q So when it says, "Larger pores limit the
8 fibrosis process to the perifilament region, the pores
9 get filled with fat."

10 Did you see that in the article?

11 A Yeah. I --

12 Q The reference is number 38. That was not
13 read to you either from this Jan Deprest article.

14 Let's look and see what reference 38 is
15 regarding larger pores.

16 A I'm lost.

17 Q I've got you. I'll show it to you.

18 MR. ANDERSON: May I approach, Your Honor?

19 THE COURT: Uh-huh.

20 BY MR. ANDERSON:

21 Q Do you see 38?

22 A Klinge, Klosterhalfen, Birkenhauer. It's our
23 publication in 2002.

24 Q Is that one of the articles that we went
25 through with the jury at the earlier part of this day?

3608

1 A Exactly.

2 Q And is that the one where you first
3 reported that in order to get large porous -- in order
4 to get fat tissue, good tissue to grow in, that you
5 needed --

6 A Yes.

7 Q -- greater than 1 millimeter?

8 A Yes.

9 Q So it's not until you get to 1,000 microns;
10 is this correct, sir?

11 A Yes.

12 Q It's not till you get to 1,000 microns, Dr.
13 Klinge, that you actually get good tissue. Correct?

14 A Exactly.

15 Q He was showing you that Amid
16 classification. If we took and went off the chart this
17 way, that's where Dr. Amid's classification would be.
18 Correct?

19 A Yes.

20 Q And that was before there were lighter
21 weight, larger pore meshes. Correct?

22 A At that time, there haven't been any.

23 Q His classification was only for
24 heavyweight, small pore meshes. Correct?

25 A Yes.

1 Q Because they didn't have lightweight, large
2 pore meshes at the time, did they?

3 A No, they didn't.

4 Q Not until the next year when you came out
5 with the lightweight, large pore concept that they
6 helped you develop. Correct?

7 MR. GAGE: Objection, leading.

8 THE WITNESS: That is correct.

9 THE COURT: The objection is overruled.

10 THE WITNESS: In December I talked to --

11 BY MR. ANDERSON:

12 Q No question pending. It's okay.

13 Did you want to say something about that?

14 A No.

15 Q Okay. Defense counsel also showed you the
16 Muhl article, and he read you some very similar things.
17 He said, "Pore sizes of 500 to 600 microns permit
18 ingrowth of soft tissue."

19 And then he said, you didn't test -- you
20 didn't test the Prolift at 1,000 -- at 500 to 600, you
21 tested it at 1,000.

22 Do you remember that part of your
23 testimony?

24 A Yes, yes.

25 Q Why did you test it at 1,000 and not 500 to

3610

1 600?

2 A We wanted to identify the area where we don't
3 have this scar, because in some patients, the scar is a
4 problem, and, therefore, we want to identify what is a
5 risk of a device to initiate scar tissue. And
6 therefore, we took the cutoff of 1,000.

7 Q And that's for polypropylene. Correct?

8 A That's for polypropylene.

9 Q And then he pointed out that you used a
10 different standard for the DynaMesh?

11 A Yes.

12 Q Why did you use a different one for
13 DynaMesh?

14 A We -- it was another polymer. We started to work
15 on it in 1998.

16 Q What's that made out of?

17 A It's polyvinylidene fluoride.

18 Q Called PVDF?

19 A PVDF. It has two fluorine atoms added a little
20 bit more hydroflow but is said to be more stable. And
21 in our first experience, we saw that the foreign body
22 reaction, this infiltrate and the fibrosis, that this
23 area is smaller with the PVDF than with the
24 polypropylene.

25 Q So in other words, the tissue, you have a

1 greater inflammatory response to polypropylene meshes
 2 than you do to PVDF meshes. Correct?
 3 A In comparison to PVDF. And, therefore, for the
 4 PVDF, the pores can be smaller to prevent this scarring
 5 integration.
 6 Q The jury has heard a little bit about
 7 Project Thunder. Project Thunder was the project that
 8 Ethicon was looking at as one of the alternatives to
 9 replace Gynemesh PS. Do you recall that?
 10 A Yes, yes.
 11 Q Project Lightning was something they were
 12 looking at to replace Gynemesh PS, and that was
 13 Prolift+M. Is that your understanding?
 14 A Yes.
 15 Q And then they were also looking at Project
 16 Thunder. Correct?
 17 A Yes.
 18 Q The material they were looking at in
 19 Project Thunder was PVDF, wasn't it?
 20 A Yes, yes, exactly.
 21 Q You helped do some of those studies.
 22 Correct?
 23 A Yes.
 24 Q In fact, who provided you the PVDF samples
 25 when you did your first comparison to PVDF versus

3612

1 polypropylene?
 2 A The first PVDF mesh came from Ethicon.
 3 Q Before I go into the Thunder document, you,
 4 in that 1,000 explant article that we were looking at,
 5 it said that the 1,000 microns could be speculative.
 6 You didn't get a chance to explain that. Please
 7 explain that to the jury.
 8 A We made -- or there is some data that
 9 1,000 microns are the cutoff, but it is possible that
 10 if you have additional surgical trauma to this, that
 11 this limit of 1,000 is maybe not the best to
 12 differentiate good meshes from the bad meshes. And,
 13 therefore, we offer or we said in this manuscript that
 14 you have to study it further on. We made -- we have
 15 some evidence that the cutoff is about 1,000, but there
 16 may be some other conditions where this may be
 17 modified. But this has to be done, and we offer --
 18 and, therefore, we published it because we offered this
 19 as a technology for everyone, for every manufacturer to
 20 work on this.
 21 Q Thank you for explaining that.
 22 Can we go to Plaintiff's 1664?
 23 We were talking about Project Thunder and
 24 Project Lightning. Correct?
 25 A Yes.

1 Q Could you please go back to Plaintiff's --
 2 the slide 50 on that, please, the very last one.
 3 Look at the top there. "Lightning." They
 4 said that they could "maybe have that in 12 months or
 5 less. It's a quick hit, modification to our existing
 6 product, likely naked Ultrapro."
 7 That would be once the Monocryl sutures
 8 absorbed and it would actually have large pores.
 9 Correct?
 10 A That is simply taking a hernia mesh and placing
 11 it again in the pelvic floor.
 12 Q But the Ultrapro pores were 4 to
 13 5 millimeters. Correct?
 14 A Yes. Rather large pores.
 15 Q They didn't have those bars running through
 16 them, did they?
 17 A No, they didn't.
 18 Q And it was almost half the weight of
 19 Gynemesh PS. Correct?
 20 A Yes, yes.
 21 Q So if you're looking for a lighter weight,
 22 larger pore mesh than Gynemesh PS, they had it?
 23 A They had it. And Ultrapro is the most often used
 24 mesh for hernia surgery.
 25 Q And if you go to the final -- keep that up.

3614

1 Take the bottom bullet point, please.
 2 But Project Thunder was going to take a
 3 little longer. "The holy grail of pelvic floor repair
 4 meshes, a new weave, matched to the tissue properties
 5 of native tissue."
 6 Do you see that?
 7 A Yes.
 8 Q And we saw the slide earlier that said
 9 there was no patient-centric graft material?
 10 A Yes.
 11 Q And that's why they were looking at this?
 12 A Yes, exactly.
 13 Q Is this what you were telling the jury
 14 earlier about that you need to look at the
 15 physiological requirements of the area of the body
 16 where you're going to place mesh?
 17 A Yeah. This is in line with this. But it
 18 obviously takes three years or four years to develop
 19 this.
 20 Q And how long did it take to develop, for
 21 instance, Vypro hernia?
 22 A Vypro was ready within three years.
 23 Q And Ultrapro was how long?
 24 A It was about five years.
 25 Q So if this was going to be the holy grail

1 of pelvic floor repair mesh materials and they knew
 2 they had a problem with Gynemesh PS, does this apply to
 3 what you said earlier, stop and study?
 4 A Yeah. It's a good -- perfect option.
 5 Q And this was going to be made out of the
 6 PVDF that had less inflammatory response according to
 7 your studies?
 8 A This is completely in line with what we said.
 9 Q But did you see the documents in Ethicon's
 10 documents where they said that they killed Project
 11 Thunder? Correct?
 12 A Yes.
 13 Q You were asked some questions about Prof.
 14 Muhl's testing with the DynaMesh versus the Gynemesh
 15 PS. Correct?
 16 A Yes.
 17 Q That we did for this litigation and for the
 18 jury?
 19 A Yes.
 20 Q When you put 3 pounds of force or placed on
 21 the Gynemesh PS, did it curl and rope and bend?
 22 A Yes.
 23 Q No. On the -- I'm sorry. On the Gynemesh.
 24 A On the Gynemesh, yes.
 25 Q On the Gynemesh, we saw how when you put 1

1 to 3 pounds of force, that it pulled it and there were
 2 pore deformation. Correct?
 3 A Yes.
 4 Q Did that happen to the DynaMesh that's made
 5 out of PVDF?
 6 A No, it did not, but it was intended not to do
 7 this, so it --
 8 Q Do you mean DynaMesh was made not to do
 9 this?
 10 A Yes. It was the purpose not to show this
 11 collapse of pores when there is some strain to it.
 12 Q So you -- and DynaMesh has arms like
 13 Gynemesh. Correct?
 14 A No. The arms were specifically or were made in a
 15 standard way. In the Gynemesh, the arms, it was just
 16 cut off a huge piece of a larger mesh. And if you are
 17 looking to the arms, they are looking quite different
 18 at every centimeter. So it will be hardly possible to
 19 define any property of these arms, because sometimes
 20 the filaments are running like this, sometimes like
 21 this. So always different flexibility, stretchability,
 22 so -- and in the DynaMesh, it is made very strict and
 23 very standardized. But it was by intention again.
 24 Q So DynaMesh, PVDF, did you see in the
 25 Ethicon documents where they indicated what they wanted

1 was a scar net, not a scar plate, that was the design
 2 intent of Gynemesh PS?
 3 A Yes, yes, yes.
 4 Q From your review and all of the work that
 5 you've done, were they able to achieve just a scar net,
 6 or does Gynemesh PS turn into a scar plate?
 7 A No, they were not able to produce this. And I
 8 never, ever -- well, I not ever saw the data that they
 9 tried it, to make these modifications. What happens if
 10 the pore size is increased by 30 percent? If there --
 11 one of these crossing bars is removed, what happens?
 12 All these data, I didn't find it.
 13 Q For the DynaMesh made out of PVDF, is this
 14 the construction, regular-sized pores in squares?
 15 A Roughly, but --
 16 Q And when you put 3 pounds of weight, it
 17 doesn't lose its structure, did it, in your testing?
 18 A Yes. It is intended to have this high structural
 19 stability, because it is intended to be placed in an
 20 area where a mechanical strain is applied.
 21 Q But the Gynemesh PS has bars running all
 22 through it here, here, here, here. Correct?
 23 A Yes.
 24 Q It has four bars running through each pore.
 25 Correct?

1 A Yes.
 2 Q And when it's put to the test on 3 pounds,
 3 what happens to it?
 4 A Yeah. The pores collapse. But, therefore, we
 5 have a big institute for textile engineering because
 6 it's a science. There are people who are studying it,
 7 not the surgeons. So I have to admit, there is my
 8 limit. I just have to go to them and ask them how to
 9 realize what is necessary.
 10 Q You were shown some results from a
 11 polypropylene study that you did. And although the
 12 pore design was not named, defense counsel said, well,
 13 isn't this -- doesn't this look like --
 14 MR. ANDERSON: I can approach, please, Your
 15 Honor?
 16 THE COURT: You can.
 17 BY MR. ANDERSON:
 18 Q Doesn't this look like Gynemesh PS? In
 19 fact, it's only got one bar running through the middle
 20 of the pore, doesn't it?
 21 A Therefore, it is similar, but I'm not sure.
 22 Q It's not the same, it doesn't have four
 23 bars running through it, does it?
 24 A Yes, you're right. You're right.
 25 Q You told the jury before if it has four

1 bars running through it, it brings the inflammation
 2 into the pores. Correct?
 3 A Yes.
 4 Q It will have a greater inflammatory
 5 response?
 6 A Yes.
 7 Q Fibrotic bridging?
 8 A Yes.
 9 Q Scar plates?
 10 A Yes.
 11 Q Shrinkage?
 12 A Of course.
 13 Q Patient complications?
 14 A Yes.
 15 Q This here, it's dense. This was shown to
 16 you and put on the screen. Do you remember that?
 17 A Yes.
 18 Q And they drew a line over here and said,
 19 well, this is 2.5 millimeters and this is
 20 1.75 millimeters. So we've got a big pore. Do you
 21 remember that?
 22 A Yes.
 23 Q In that big pore, they have all kinds of
 24 fibers and lines running through it that you told the
 25 jury before would bring fibrosis into that pore.

3620

1 Correct?
 2 A Yeah.
 3 Q Did you read the testimony of Dan Burkley,
 4 the porosity tester for Ethicon?
 5 A We have shown it.
 6 Q And you've read his deposition. Correct?
 7 A Yep.
 8 Q Do you recall he said he has no idea where
 9 those numbers came from that you see here?
 10 MR. GAGE: Objection, Your Honor.
 11 THE WITNESS: Yes.
 12 THE COURT: The objection is sustained.
 13 The jury should disregard the last answer unless you
 14 intend to play it for the jury.
 15 BY MR. ANDERSON:
 16 Q You were shown this by defense counsel, one
 17 of the many hernia articles that he showed you.
 18 Let me ask you this. Any of your hernia
 19 articles and any of the ones he showed you, in any of
 20 them did you say that Gynemesh PS would be safe in a
 21 woman's pelvis?
 22 A No.
 23 Q Most all these articles are hernia.
 24 Correct?
 25 A Yes.

1 Q And in this study he showed you some
 2 titanium polypropylene, about biocompatibility.
 3 Correct?
 4 A Yes.
 5 Q One thing that wasn't read to you,
 6 "However, there are no data available analyzing the
 7 pure effect of titanium coating on biocompatibility in
 8 the in vivo situation." Correct?
 9 A Yes.
 10 Q So they don't know what it's going to do in
 11 a human being. Correct?
 12 A No. It's one of the studies to investigate, to
 13 study it.
 14 Q You were also shown a PTFE study comparing
 15 Optilene LP. Do you remember that?
 16 A Yes.
 17 Q What's a better indicator as to whether or
 18 not a mesh is going to be safely implanted in a woman's
 19 pelvic tissue the rest of her life? Clinical results
 20 or what it looks like in a pig after three months?
 21 A The most important aspect whether a mesh is a
 22 good mesh or a bad mesh, of course, are the clinical
 23 results. But to predict this in the -- if you want to
 24 make a development of the best meshes, we have to go to
 25 preclinical tests. And these will help us to find the

3622

1 best solution, but the most important thing is whether
 2 it really works or not. So if you have good
 3 experiments and it doesn't work because you have some
 4 patients with complaints, it will not help.
 5 And, therefore, the most critical question
 6 is if there is someone coming with shrinkage and
 7 contraction, regardless how often it is, could it have
 8 been avoided, yes or not? Did we do all our best to
 9 avoid these problems with the scar is sufficient
 10 studying of this phenomenon. And this is the most
 11 important thing. And all the other things are
 12 attempted just to help.
 13 Q You had some questions about this Jan
 14 Deprest article, about synthetic implants and that
 15 these knitted structures showed various degrees of
 16 inflammatory response.
 17 Do you remember seeing this article?
 18 A Yes, I've seen that. I mean, some way, yeah.
 19 Q I want to read to you what defense counsel
 20 didn't read.
 21 "These foreign materials induce first an
 22 acute inflammatory reaction which in the case of
 23 permanent materials transits to a chronic inflammatory
 24 reaction and fibrosis."
 25 Do you agree with that?

1 A Yes, totally. I met Jan Deprest in December in
 2 Cologne, and he -- there is no conflict in our opinions
 3 about this cutoff. And he's going to switch to PVDF.
 4 Q The cutoff, you mean 1 millimeter?
 5 A Yes. So large pore is accepted by him as well.
 6 Q And you were shown your lightweight, large
 7 pore concept article. Correct?
 8 A Yes.
 9 Q This sentence was read to you.
 10 "Bridging occurs in all mesh modifications
 11 with a granuloma size around each fiber exceeding more
 12 than half the pore size," and then defense counsel
 13 stopped. The next sentence says, "Usually the
 14 phenomenon of bridging is observed in all mesh
 15 modifications with a pore size of less than 1
 16 millimeter."
 17 Further confirmation of what we've been
 18 telling the jury here today?
 19 A Yes.
 20 Q Defense counsel showed you this e-mail from
 21 Michel Cosson to this Josh Samon. And he read to you,
 22 "Is it critical that mesh straps lay flat in the
 23 channel or is it okay to be rolled up?" And then he
 24 says, "Cosson," Dr. Cosson says, "if the mesh is in
 25 place, there is no problem for a roll-up."

3624

1 Do you remember that?
 2 A Yes.
 3 Q And you said something at the end of that
 4 about class level 5?
 5 A Yes.
 6 Q Can you explain to the jury what you were
 7 trying to talk about right there?
 8 A So we have certain degrees of the way we classify
 9 the evidence, what is the highest evidence, what gives
 10 us the best security that it is reliable advice. So
 11 there is a grading of the evidence from 1 to 5. And 5
 12 is the expert opinion. So if someone is standing up
 13 and said, okay, it's like this, without showing any
 14 data or any studies and so on, and this is, of course,
 15 the lowest level of evidence. So if you --
 16 Q Opinion versus data, is that what you're
 17 saying?
 18 A Yes, yes, exactly.
 19 Q Did you see any data --
 20 A No.
 21 Q -- after this where Ethicon actually looked
 22 at data, meaning performed studies, so that they could
 23 look at what would happen with this rolling up while
 24 going through a woman's groin and through her buttocks?
 25 Did you ever see any of that?

1 A No, I didn't see any data or any studies where
 2 this was in the focus of the project.
 3 Q So Michel Cosson, he believes that the mesh
 4 in place is no problem for a roll-up.
 5 Of course, he doesn't have the arms going
 6 through his groin, does he?
 7 MR. GAGE: Objection.
 8 THE COURT: That is argumentative and that
 9 question is stricken. The jury should disregard it.
 10 BY MR. ANDERSON:
 11 Q The point is that Ethicon did get e-mails,
 12 as we saw earlier from Dr. Eberhard, where she
 13 indicated that the patients were feeling it in their
 14 tissue. Correct?
 15 A Yes. And this is the classical situation where
 16 you have conflicting results, and then you have to
 17 study it. Otherwise, I don't know how you can get a
 18 good solution.
 19 Q You were shown an article about pelvic
 20 organ prolapse, Prolift system that was in 75 patients.
 21 Do you recall that?
 22 A Yes.
 23 Q What will this data tell you from 75
 24 patients?
 25 A So there are a lot of data with patients, 15, 20

3626

1 patients, 100 patients. And all these clinical trials
 2 help to find out whether there are some complications,
 3 but they usually have not sufficient statistical power
 4 to say any more, to say what is the safety of these --
 5 of this device. And, therefore, the value of these
 6 clinical trials is too low to say, okay, you made an
 7 evaluation and that is reality.
 8 Q And what wasn't read to you, I want to read
 9 to you now and see if you agree.
 10 "Numerous studies have reported on
 11 short-term outcomes" --
 12 MR. GAGE: Objection, Your Honor, I was not
 13 allowed to go into this.
 14 MR. ANDERSON: Certainly was.
 15 THE COURT: Well, let's approach.
 16 - - -
 17 (The following occurred at sidebar:)
 18 MR. ANDERSON: I showed the other thing
 19 that he went into. He showed Milani, he showed the
 20 cover of it, he read the abstract. And then he went to
 21 the numbers. And after he had gone through the numbers
 22 for a long time, we finally said, Your Honor, he's
 23 getting too deep into the numbers and so he was able to
 24 say Ultrapro was bigger than the other. But he was
 25 allowed to read this entire thing, but he chose not to

1 read that.
 2 THE COURT: Okay. I'll allow you to use
 3 just the first sentence it says long-term studies -- it
 4 doesn't appear to be too detailed, but it's
 5 appropriate.
 6 MR. ANDERSON: Thank you.
 7 - - -
 8 (The sidebar ended.)
 9 - - -
 10 BY MR. ANDERSON:
 11 Q The sentence that wasn't read to you is,
 12 "Numerous studies have reported on short-term outcomes
 13 of this procedure but long-term studies are lacking."
 14 Do you agree that long-term studies were
 15 lacking on Prolift --
 16 A Definitely.
 17 Q -- when it went to market on March 2005?
 18 A This sentence can be found in many other articles
 19 as well.
 20 Q Here's another one that he showed you about
 21 tension-free vaginal mesh. What wasn't read to you is,
 22 "A long-term study on a large number of patients is
 23 still warranted to confirm and validate the clinical
 24 use."
 25 Would have been a good idea, wouldn't it?

3628

1 MR. GAGE: Objection, argumentative.
 2 MR. ANDERSON: Withdrawn.
 3 THE COURT: The objection is sustained.
 4 The jury should disregard it.
 5 BY MR. ANDERSON:
 6 Q Defense counsel spent about the first 40
 7 minutes talking about hernias. So I want to talk a
 8 little bit about that with you.
 9 If millions of people have polypropylene in
 10 one part of their body, does that mean that that
 11 polypropylene is going to be safe in another part of
 12 the body?
 13 A No. You can transfer this -- in this general --
 14 it is not adequate to say this.
 15 Q If a surgical mesh for polypropylene may be
 16 okay in one kind of hernia, does that mean it will be
 17 okay to wrap it around another organ like your eye,
 18 like your heart, like your lungs?
 19 A No, definitely not.
 20 Q Like a woman's pelvic tissue?
 21 MR. GAGE: Objection, Your Honor.
 22 THE WITNESS: Therefore, the abdominal wall
 23 situation --
 24 THE COURT: The objection is overruled. He
 25 can answer.

1 BY MR. ANDERSON:
 2 Q Go ahead.
 3 A Yeah. The abdominal wall is a completely
 4 different setting. The mesh is placed at a different
 5 place. And it is more easy to remove the mesh if you
 6 have some failures.
 7 Q Can you put up that slide, please?
 8 I want to go back, if I could -- no. The
 9 one before, please.
 10 Do you remember when we were looking at the
 11 Ethicon minutes from that 2007 Norderstedt expert
 12 meeting?
 13 MR. GAGE: Your Honor, objection. Beyond
 14 the scope of my cross.
 15 MR. ANDERSON: It's hernia surgery, Your
 16 Honor.
 17 THE COURT: I'll allow it.
 18 BY MR. ANDERSON:
 19 Q What Kirsten Spychaj said at that meeting
 20 was, "In pelvic floor surgery, shrinkage seems to be
 21 more important than in hernia surgery."
 22 Did you read that?
 23 A Yes, I read that.
 24 Q Did you agree with that as a hernia
 25 surgeon?

3630

1 A Yes. I agree to this, yeah.
 2 Q In other words, when you have contracted
 3 mesh in the hernia or in the abdomen, it's a lot
 4 different than having contracted mesh in a woman's
 5 pelvic tissue. Correct?
 6 A Yes, definitely.
 7 Q And in and around her pelvic organs?
 8 A Yes. The latter, it will be impossible to remove
 9 these.
 10 Q Let's talk about some of the difference
 11 between abdominal mesh repair and pelvic floor mesh
 12 repair, since it was brought up by defense counsel.
 13 Abdominal mesh repair, it's a flat mesh.
 14 Correct?
 15 A It's a completely flat -- or it's a flat,
 16 two-dimensional mesh. It doesn't have this
 17 three-dimensional configuration. It is usually placed
 18 without any tension. It is very often laying only in
 19 fatty tissue. It's much easier to remove in the
 20 abdominal wall. There are areas where it's difficult
 21 to remove, and there, we are very limited or we don't
 22 like it to place there a mesh, only in some desperate
 23 cases we would do so.
 24 Q Let me stop you right there.
 25 MR. GAGE: Your Honor, I object. Pelvic

1 floor mesh repair is clearly not his area of specialty.
 2 He shouldn't even talk about -- what's on the left,
 3 that's what I covered with him, but on the right, he
 4 shouldn't because he's not qualified.

5 MR. ANDERSON: He's been asked article
 6 after article about meshes in pelvic floor repair.

7 MR. GAGE: But not like that, Your Honor.
 8 Not going through that sort of stuff. And he's trying
 9 to convert over into a pelvic surgeon, which he's
 10 clearly not.

11 MR. ANDERSON: I absolutely disagree.

12 THE COURT: I think he's still talking
 13 about the quality of the material itself and how the
 14 material is used. Therefore, I'm going to allow it.

15 MR. ANDERSON: Thank you, Your Honor.

16 BY MR. ANDERSON:

17 Q So let's look at the first one. A flat
 18 mesh laying in the abdomen, like defense counsel
 19 pointed out earlier. Correct?

20 A Yes.

21 Q Whereas when you talk about a
 22 three-dimensional mesh, do you mean going in and around
 23 the pelvic organs, out through the woman's groin and
 24 down through her buttocks?

25 A Yes.

3632

1 Q And when you say without tension, you can
 2 lay that abdominal mesh flat like this. Correct?
 3 A Yeah. It's flat. We don't even use any
 4 fixation. It is just placed between the tissue, and
 5 usually it stays there. There are no arms or something
 6 putting on some mechanical strain.

7 Q And you said this is laying in fatty tissue
 8 versus the female organs where there's a lot of nerves.
 9 So instead of laying here, it's going all through here
 10 where there's lots of different nerve endings, nerve
 11 channels and nerve branches. Correct?

12 A Yes. We are happy as an abdominal wall surgeon
 13 that we can place the mesh in this layer of fat tissue
 14 where there are little nerves and where the reaction is
 15 quite smooth.

16 Q I think one of the big points you just
 17 raised a minute ago that I want to go to is, it's
 18 easier to remove this flat mesh in the abdomen and
 19 almost impossible to remove the mesh from a woman's
 20 vagina and in and around her pelvic organs.

21 Is that your understanding as a hernia
 22 surgeon, that it's easier to remove here?

23 MR. GAGE: Objection, qualifications. He's
 24 deep into pelvic floor surgery.

25 THE COURT: Doctor, do you have the

1 experience or expertise to discuss whether it's
 2 difficult to remove mesh from the pelvic area?

3 THE WITNESS: I know from all documents
 4 where the specialists in the pelvic floor surgery said
 5 that it is almost impossible to remove it. I know from
 6 the abdominal wall that --

7 THE COURT: I'll allow you to give your
 8 opinion based on your review of the materials.

9 MR. ANDERSON: Thank you. I was actually
 10 just moving to the last bullet point.

11 BY MR. ANDERSON:

12 Q You talked about in hernia, with repairing
 13 an abdominal hernia mesh, if you have a hernia that's
 14 like this, you actually, if the place that you want to
 15 repair is here, you said you have to have 5 centimeters
 16 extra around the edges of the area that you want to
 17 repair; is that correct?

18 A That is correct. That is a principle.

19 Q And why do hernia surgeons have to do that
 20 with polypropylene meshes?

21 A Because we know that there will be considerable
 22 shrinkage, that this mesh will become smaller. And if
 23 it's too small, then you will have a recurrence and
 24 another hernia. And, therefore, we want to make this
 25 wide overlap. And if you place it in the abdominal

3634

1 wall, there is much space to do so.

2 Q The Gynemesh PS is precut. Correct?

3 A Yes.

4 Q Is there any way to allow for the shrinkage
 5 if it's precut? If it's already cut in this fashion,
 6 there's no way to allow for the shrinkage in order to
 7 make sure it covers the organs, is there?

8 A I have no idea how this may work.

9 Q You said earlier that there are certain
 10 types of hernia repair where you absolutely would not
 11 use polypropylene mesh. Correct?

12 A Not absolutely, but very restrictive in our
 13 limitations.

14 Q And one of those is around the esophagus
 15 where you have a hiatal hernia. Correct?

16 A Yes, yes, yes. We know that when we place a
 17 mesh, the recurrence rate is lower. We know this, but
 18 there are some patients where it may come that the mesh
 19 migrates into the esophagus and cut off -- yeah,
 20 migrates into -- made an erosion into the esophagus.

21 And the reoperation is a big challenge, and --
 22 sometimes with mortality, and, therefore, it is a
 23 common agreement among abdominal surgeons not to use it
 24 as a first choice, but only in patients where it -- we
 25 don't know what to do else, then we use the mesh.

1 Q Can you put the last slide up, please?
 2 Have you seen this slide by the worldwide
 3 medical affairs director, David Robinson at Ethicon,
 4 "The vagina is not the abdomen nor similar to any other
 5 surgical environment"? Do you agree with that, sir?
 6 A Yes.
 7 MR. GAGE: Same objection, Your Honor, as
 8 to the timing after date of surgery, I believe.
 9 MR. ANDERSON: No. It predates it. This
 10 is when Dr. Robinson --
 11 THE COURT: It does predate it? The
 12 objection is overruled.
 13 MR. ANDERSON: Yes, ma'am.
 14 BY MR. ANDERSON:
 15 Q Do you agree with that?
 16 A Yes.
 17 THE COURT: Counsel, if you only have a few
 18 more minutes, otherwise we're going to have to bring
 19 the jury back tomorrow and --
 20 MR. ANDERSON: Last question. Last
 21 question.
 22 BY MR. ANDERSON:
 23 Q Do you agree with that statement?
 24 A Yes.
 25 MR. ANDERSON: No further questions.

3636

1 - - -
 2 RECROSS-EXAMINATION
 3 - - -
 4 BY MR. GAGE:
 5 Q Sir, you talked about a spreadsheet of over
 6 1,000 implants. As far as you know, not a single one
 7 of them was Prolift or Gynemesh. Correct?
 8 A Yes.
 9 Q Dr. Cosson's e-mail, he's a
 10 urogynecologist, he's a surgeon, he implants Prolifts
 11 and you do not. Correct?
 12 A Yes.
 13 Q PVDF mesh, you've constructed a mesh in the
 14 pelvic floor made out of PVDF. For pelvic floor
 15 repair, there are no studies that you're aware of that
 16 demonstrate that PVDF mesh is superior to polypropylene
 17 mesh. Correct?
 18 A Yes.
 19 Q And, sir, you were shown this. Do you
 20 remember?
 21 A Yes.
 22 Q Talked about the bar going down the middle?
 23 A Yeah.
 24 Q You said that can't be 2.5 millimeter,
 25 that's the wrong way to measure it. Right?

1 A Yes.
 2 Q This is your article, we showed it, jury
 3 saw it, 2004, it's got your name on it. Correct?
 4 That's one of the ones we went through earlier?
 5 A Yes.
 6 Q There's the picture, mesh with a bar going
 7 down the middle of it?
 8 A Yes.
 9 Q And the numbers 2.5 appear there.
 10 And, sir, my question to you is, you were
 11 the author of the article. Who put the 2.5 in your
 12 article?
 13 A Is the question to me?
 14 Q Yes.
 15 A Sorry.
 16 Q You're the author of the article. It's
 17 got --
 18 A I'm a co-author --
 19 Q It's got 2.5 in your article. Correct?
 20 A Yes. It is an article for surgeons.
 21 Q You were asked a question that -- about
 22 TiMesh.
 23 You were shown one of the dog studies and
 24 they said, this is a dog study, it's not a human study.
 25 Right? Do you remember that just a second ago, Mr.

3638

1 Anderson?
 2 A No, I don't.
 3 THE COURT: I think he said it wasn't a pig
 4 study.
 5 MR. GAGE: It wasn't a pig study.
 6 THE COURT: I think he asked him about a
 7 pig study, but go ahead.
 8 BY MR. GAGE:
 9 Q He said it was a pig study.
 10 In fact, sir, I actually showed you a
 11 TiMesh article that was a randomized, controlled,
 12 single-center clinical trial involving 102 patients,
 13 didn't I?
 14 A Yeah. I had several discussions with Prof.
 15 Klosterhalfen about the value of this study.
 16 Q And that article found that TiMesh, and we
 17 read the conclusion, it was a light titanium covered
 18 polypropylene mesh, it was associated with less
 19 postoperative pain in the short term, lower analgesic
 20 consumption and a quicker return to everyday
 21 activities. Do you remember we went through that?
 22 A TiMesh is specifically designed for the hernia,
 23 and it is not a very bad mesh.
 24 Q And so Optilene, 0 percent effective
 25 porosity, good integration, no bridging scar tissue,

1 good biocompatibility.
 2 We pulled those quotes out of articles.
 3 Correct? That's my question to you. We pulled those
 4 quotes out of articles that we showed the jury.
 5 Correct?
 6 A Yeah, yeah. You took it out.
 7 Q And TiMesh, 0 percent effective porosity,
 8 good biocompatibility, less postoperative pain, quicker
 9 return to everyday activities and best
 10 biocompatibility.
 11 In fact, we pulled those out of articles.
 12 Correct?
 13 A Both in a specific setting of experiments.
 14 Q And then here we had Gynemesh and Prolift
 15 and you said with strain, it's got 0 percent effective
 16 porosity, and then I showed you a biopsy article of
 17 women who had Prolift meshes that you had never seen
 18 before, and biocompatibility was satisfactory according
 19 to those pelvic surgeons. Correct?
 20 A If you look --
 21 Q Is my question true, yes or no? That's
 22 what the authors concluded, biocompatibility was
 23 satisfactory, yes or no?
 24 A That is not justified, because they only have a
 25 very small --

3640

1 MR. GAGE: Your Honor, it's a yes or no
 2 question.
 3 THE COURT: The question is just is that
 4 what the authors -- did that language come from that
 5 article?
 6 THE WITNESS: If you read it completely,
 7 yes.
 8 MR. GAGE: Your Honor --
 9 BY MR. GAGE:
 10 Q My question was yes or no, those words
 11 appear in that article?
 12 A Yes.
 13 MR. GAGE: Nothing further.
 14 - - -
 15 REDIRECT EXAMINATION
 16 - - -
 17 BY MR. ANDERSON:
 18 Q What were you trying to explain right there
 19 he wasn't allowing you?
 20 A If you look to "Material and Methods" there, they
 21 are looking to an area of 58 square microns. That is a
 22 very, very tiny area. So you need more patients. The
 23 power of this study is very, very low, and you have to
 24 look to a wider area of tissue, not only these 60
 25 square millimeters. That's within the inflammatory

1 infiltrate. So what to learn from this? I don't know
 2 it.
 3 Q Counsel just pointed out, he showed you
 4 your article and said you were the author of this, sir,
 5 2.5 millimeters. You were the author in 2004. Do you
 6 remember that?
 7 A The point was --
 8 Q Do you remember that question?
 9 A Yes.
 10 Q That was before you had a chance to look at
 11 15,000 pages of internal Ethicon documents and
 12 determine that 2.5 is wrong; isn't that correct?
 13 A That is correct.
 14 MR. GAGE: Objection, Your Honor.
 15 THE COURT: That is leading.
 16 MR. ANDERSON: No further questions.
 17 THE COURT: Objection sustained. The
 18 question and answer are stricken.
 19 Okay. The jury can go out and if the jury
 20 has any -- unless, Mr. Gage, did you have anything
 21 else?
 22 MR. GAGE: No, Your Honor.
 23 THE COURT: Then the jury can go out, we'll
 24 see if they have any questions.
 25 - - -

3642

1 (The jury leaves the courtroom.)
 2 - - -
 3 THE CLERK: No questions.
 4 THE COURT: 9:30 tomorrow.
 5 - - -
 6 (Witness excused.)
 7 - - -
 8 (Adjourned at approximately 5:01 p.m.)
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CERTIFICATION

I, ANN MARIE MITCHELL, CCR, RDR, CRR, Realtime
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compressed transcript to the best of my knowledge and
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<p>\$100 [1] - 3406:20 \$100,000 [2] - 3407:9, 3493:7 \$500 [1] - 3406:21 '04 [1] - 3413:3 '05 [5] - 3413:3, 3515:7, 3560:14, 3562:12, 3562:13 '06 [1] - 3439:4 '07 [1] - 3559:24 '08 [2] - 3413:9, 3416:13 '09 [2] - 3413:9, 3416:13 '10 [1] - 3416:13 '11 [1] - 3416:13 '12 [1] - 3416:13 '80s [1] - 3394:9 '86 [2] - 3510:11, 3511:12 '90s [5] - 3382:24, 3383:1, 3458:22, 3460:3, 3498:2 '93 [1] - 3388:13 '94 [3] - 3560:11, 3562:5, 3562:6 '97 [1] - 3511:13 '98 [2] - 3459:10, 3562:7 '99 [2] - 3459:10, 3562:7 0 [9] - 3556:19, 3557:22, 3558:3, 3567:7, 3586:5, 3586:7, 3638:24, 3639:7, 3639:15 0689 [1] - 3600:1 07068 [1] - 3376:5 07962 [1] - 3377:5 1 [61] - 3420:8, 3424:12, 3424:20, 3425:3, 3426:18, 3447:10, 3447:14, 3447:17, 3448:10, 3452:20, 3459:12, 3459:24, 3460:1, 3460:8, 3460:21, 3464:6, 3464:9, 3464:11, 3468:9, 3468:13, 3469:1, 3469:22, 3472:4, 3472:22, 3472:24, 3473:9, 3473:21, 3475:15, 3475:23, 3477:11, 3478:12, 3481:11, 3481:18, 3481:22, 3523:14, 3553:19, 3556:7, 3556:8, 3556:22, 3556:24, 3557:4,</p>	<p>3557:7, 3557:19, 3557:22, 3567:1, 3573:14, 3580:22, 3580:25, 3587:12, 3588:5, 3588:24, 3591:19, 3591:24, 3602:10, 3602:15, 3603:19, 3608:7, 3615:25, 3623:4, 3623:15, 3624:11 1,000 [42] - 3457:7, 3474:16, 3557:2, 3557:6, 3557:7, 3573:13, 3580:23, 3588:5, 3588:20, 3588:21, 3588:23, 3589:2, 3589:7, 3589:11, 3591:20, 3595:23, 3596:16, 3597:3, 3597:13, 3598:18, 3599:2, 3599:14, 3600:11, 3601:15, 3601:24, 3602:1, 3602:8, 3602:22, 3602:23, 3603:19, 3608:9, 3608:12, 3609:20, 3609:21, 3609:25, 3610:6, 3612:4, 3612:5, 3612:9, 3612:11, 3612:15, 3636:6 1,000-micron [2] - 3599:7, 3599:11 1,750 [1] - 3574:1 1-20 [1] - 3375:6 1.36 [2] - 3493:12, 3493:24 1.6 [2] - 3476:7, 3478:12 1.65 [3] - 3476:5, 3478:11, 3478:22 1.75 [1] - 3619:20 10 [9] - 3376:15, 3380:2, 3400:8, 3435:13, 3523:24, 3525:2, 3554:10, 3591:23, 3606:3 100 [7] - 3382:20, 3384:14, 3398:1, 3406:10, 3420:10, 3420:15, 3626:1 100,000 [3] - 3493:15, 3493:16, 3493:25 10016 [1] - 3376:15 102 [1] - 3638:12 1020 [1] - 3376:20 103 [1] - 3376:4 104.2 [1] - 3575:14</p>	<p>104.6 [1] - 3578:3 105 [1] - 3545:12 10:05 [1] - 3408:25 10:35 [1] - 3409:1 11 [1] - 3595:1 11/23/05 [1] - 3484:10 111 [1] - 3549:12 12 [10] - 3478:8, 3489:21, 3509:22, 3510:6, 3510:8, 3510:9, 3517:1, 3595:2, 3602:1, 3613:4 1201 [1] - 3375:9 127 [1] - 3536:4 12:28 [1] - 3492:11 130 [1] - 3399:1 131 [1] - 3580:7 136,000 [1] - 3494:1 1360 [1] - 3376:10 139.4 [1] - 3594:1 14 [1] - 3562:8 140.3 [1] - 3595:9 1400 [1] - 3376:20 142 [3] - 3509:22, 3510:7, 3511:10 15 [8] - 3400:8, 3406:17, 3472:1, 3525:2, 3562:8, 3604:7, 3606:3, 3625:25 15,000 [1] - 3641:11 15-minute [1] - 3554:10 150 [2] - 3406:10, 3531:22 150.2 [1] - 3585:6 150.6 [1] - 3585:16 160,000 [1] - 3494:12 1664 [1] - 3612:22 170.5 [1] - 3510:21 182 [2] - 3568:4, 3568:17 1944 [1] - 3500:24 1958 [1] - 3503:19 1959 [1] - 3503:20 1960s [3] - 3512:22, 3513:6, 3514:13 1962 [3] - 3504:5, 3504:6, 3504:22 1963 [2] - 3505:2, 3505:11 1967 [2] - 3505:19, 3505:22 1975 [2] - 3514:17, 3515:13 1977 [3] - 3380:25, 3511:9, 3511:13 1980s [3] - 3510:8,</p>	<p>3510:14, 3532:10 1981 [1] - 3592:17 1982 [2] - 3592:9, 3592:11 1983 [1] - 3381:1 1985 [1] - 3498:5 1986 [1] - 3510:10 1988 [1] - 3592:14 1990s [1] - 3532:11 1992 [1] - 3511:10 1993 [8] - 3381:19, 3382:13, 3383:19, 3383:20, 3385:10, 3387:2, 3387:11, 3392:19 1994 [6] - 3393:5, 3395:9, 3395:21, 3560:3, 3560:10, 3562:11 1995 [5] - 3392:4, 3392:17, 3393:17, 3425:24, 3534:15 1997 [4] - 3457:12, 3562:15, 3574:12, 3574:18 1998 [10] - 3420:19, 3421:21, 3422:16, 3499:14, 3508:20, 3510:4, 3510:7, 3510:9, 3562:15, 3610:15 1999 [4] - 3382:13, 3422:15, 3423:15, 3511:22 19th [1] - 3500:14 1:00 [1] - 3492:7 1:12 [1] - 3492:12 2 [9] - 3448:10, 3453:11, 3464:1, 3474:21, 3483:14, 3483:15, 3523:15, 3524:4, 3575:15 2,000 [2] - 3398:5, 3398:8 2,530 [2] - 3573:8, 3573:19 2.3 [1] - 3462:23 2.5 [11] - 3576:14, 3576:16, 3577:4, 3578:1, 3619:19, 3636:24, 3637:9, 3637:11, 3637:19, 3641:5, 3641:12 2.5-millimeter [1] - 3469:23 2.5-millimeters [1] - 3469:25 20 [34] - 3393:23, 3394:22, 3395:4, 3400:3, 3402:9,</p>	<p>3402:10, 3404:7, 3404:19, 3428:8, 3440:3, 3441:1, 3443:8, 3447:7, 3453:2, 3459:25, 3474:20, 3474:25, 3475:6, 3475:9, 3482:22, 3491:3, 3491:7, 3498:24, 3505:1, 3519:21, 3522:16, 3523:12, 3523:18, 3523:23, 3524:18, 3524:19, 3524:23, 3564:25, 3625:25 20,000 [1] - 3406:18 20-year [1] - 3525:2 20.5 [2] - 3517:10, 3517:21 200 [5] - 3391:18, 3397:21, 3399:1, 3406:23, 3588:12 2000 [20] - 3383:7, 3384:3, 3385:10, 3387:2, 3387:8, 3387:11, 3388:13, 3388:18, 3391:25, 3430:11, 3433:3, 3436:18, 3439:23, 3447:16, 3511:21, 3515:2, 3515:11, 3515:16, 3516:16, 3601:22 2000s [1] - 3460:3 2001 [1] - 3578:17 2002 [10] - 3389:15, 3424:1, 3424:15, 3424:17, 3424:24, 3426:14, 3459:11, 3515:4, 3515:22, 3607:23 2003 [5] - 3389:24, 3434:23, 3436:5, 3436:20, 3449:10 2003-2004 [1] - 3437:9 2004 [12] - 3390:7, 3409:19, 3411:5, 3435:13, 3436:5, 3436:23, 3449:11, 3498:2, 3542:24, 3575:7, 3637:3, 3641:5 2005 [46] - 3385:6, 3385:7, 3392:4, 3392:18, 3393:17, 3409:19, 3411:5, 3411:13, 3411:21, 3412:11, 3415:6, 3415:7, 3417:9,</p>
--	--	--	---	---

3418:15, 3419:1,
3425:17, 3425:25,
3429:13, 3429:22,
3451:8, 3462:14,
3463:23, 3467:12,
3468:8, 3468:23,
3473:7, 3473:17,
3477:4, 3482:3,
3483:3, 3488:19,
3491:18, 3491:25,
3498:3, 3532:11,
3545:10, 3552:10,
3552:11, 3560:15,
3560:16, 3560:20,
3593:23, 3594:11,
3594:18, 3594:24,
3627:17
2006 [18] - 3389:24,
3391:1, 3409:19,
3411:6, 3439:1,
3439:14, 3449:3,
3449:16, 3453:11,
3469:10, 3498:6,
3498:7, 3498:10,
3532:13, 3532:14,
3594:11, 3594:18,
3594:23
2007 [13] - 3449:18,
3453:10, 3473:17,
3477:21, 3479:15,
3555:21, 3555:25,
3556:15, 3567:1,
3572:1, 3587:14,
3588:3, 3629:11
2008 [4] - 3409:20,
3411:10, 3482:2,
3482:9
2009 [6] - 3391:1,
3411:10, 3411:12,
3412:10, 3467:9,
3582:9
2010 [4] - 3411:10,
3412:10, 3413:9,
3494:11
2011 [1] - 3405:17
2012 [19] - 3493:17,
3493:18, 3493:23,
3535:4, 3535:21,
3556:16, 3557:11,
3558:17, 3559:5,
3559:7, 3564:1,
3569:14, 3572:1,
3586:12, 3588:19,
3589:7, 3596:4,
3601:23
2013 [1] - 3375:11
212 [2] - 3376:16,
3505:24
215 [1] - 3376:10
216 [1] - 3376:11

22 [1] - 3480:23
220 [1] - 3597:24
2257.46 [1] - 3572:5
228-9898 [1] - 3376:6
25 [3] - 3401:10,
3470:14, 3542:24
250 [2] - 3391:18,
3475:15
2530 [1] - 3572:24
254 [1] - 3536:3
259.3 [1] - 3580:8
259.7 [1] - 3581:4
26 [5] - 3472:6,
3476:1, 3476:2,
3586:5, 3586:7
261.6 [1] - 3596:7
266.11 [1] - 3571:12
266.9 [1] - 3549:13
28 [3] - 3385:3,
3385:4, 3533:7
285 [1] - 3565:25
29 [1] - 3558:1
2:36 [1] - 3554:15
2:58 [1] - 3554:16
3 [9] - 3421:15,
3454:7, 3459:2,
3476:5, 3481:13,
3615:20, 3616:1,
3617:16, 3618:2
3.3 [1] - 3478:17
30 [11] - 3403:5,
3406:12, 3421:12,
3422:17, 3422:18,
3422:20, 3422:23,
3480:10, 3519:21,
3540:18, 3617:10
300 [10] - 3440:13,
3443:16, 3520:19,
3520:20, 3520:21,
3521:2, 3523:3,
3530:18, 3534:3,
3588:12
300-400 [1] - 3440:21
30XI00212000 [1] -
3643:5
323 [1] - 3536:4
330 [2] - 3399:3,
3399:9
3379 [1] - 3378:6
3405 [1] - 3378:6
3492 [1] - 3378:6
35 [2] - 3401:10,
3507:14
3597 [1] - 3378:6
360.3 [1] - 3587:24
360.5 [1] - 3588:10
360.7 [1] - 3586:16
3636 [1] - 3378:6
3640 [1] - 3378:7
372 [2] - 3540:25,

3541:2
38 [3] - 3607:12,
3607:14, 3607:21
39157 [1] - 3376:21
4 [3] - 3375:11,
3481:5, 3613:12
4,000 [1] - 3448:24
4.5 [1] - 3535:11
40 [2] - 3403:5,
3628:6
400 [7] - 3440:21,
3440:22, 3521:3,
3604:24, 3605:2,
3606:5, 3606:12
40th [1] - 3376:15
42 [1] - 3558:7
44113 [1] - 3376:11
45 [4] - 3398:18,
3398:19, 3580:15,
3580:19
45.5 [1] - 3535:14
5 [15] - 3459:2,
3478:6, 3484:17,
3489:20, 3524:6,
3524:24, 3543:22,
3543:23, 3604:6,
3604:7, 3613:13,
3624:4, 3624:11,
3633:15
5-0 [1] - 3487:23
50 [16] - 3398:14,
3398:15, 3422:17,
3422:18, 3422:20,
3422:22, 3441:8,
3441:14, 3441:15,
3441:16, 3503:18,
3529:2, 3540:18,
3613:2
500 [15] - 3406:4,
3448:22, 3475:15,
3476:6, 3478:21,
3588:11, 3589:1,
3596:15, 3604:25,
3605:3, 3606:5,
3606:12, 3609:17,
3609:20, 3609:25
526 [1] - 3536:3
538-0800 [1] - 3377:5
54 [2] - 3536:23,
3536:25
541 [1] - 3504:7
56 [2] - 3568:4,
3568:17
58 [1] - 3640:21
592-8384 [1] -
3376:11
5:01 [1] - 3642:8
6 [4] - 3524:6,
3532:11, 3576:8,
3576:9

60 [1] - 3640:24
600 [8] - 3576:10,
3588:11, 3589:1,
3589:8, 3589:11,
3609:17, 3609:20,
3610:1
601 [1] - 3376:21
647.10 [1] - 3506:3
647.3 [2] - 3501:21,
3501:22
647.7 [2] - 3503:4,
3503:6
65.6 [1] - 3517:1
68-page [1] - 3407:3
7 [5] - 3470:14,
3499:21, 3543:17,
3586:16, 3604:6
75 [33] - 3457:3,
3457:7, 3457:9,
3457:19, 3457:21,
3458:3, 3458:6,
3458:7, 3458:16,
3458:20, 3461:6,
3461:7, 3461:20,
3461:24, 3470:15,
3470:17, 3536:3,
3556:25, 3574:23,
3591:15, 3591:17,
3591:22, 3591:24,
3594:3, 3595:15,
3603:19, 3604:4,
3604:10, 3604:14,
3604:20, 3605:24,
3625:20, 3625:23
750 [1] - 3592:2
779-1414 [1] -
3376:16
8 [1] - 3583:16
80,000 [1] - 3494:9
81.5 [1] - 3537:9
84 [2] - 3568:4,
3568:17
85.7 [1] - 3457:22
864.4 [1] - 3568:22
877.370.3377 [1] -
3375:24
9 [1] - 3513:2
90 [7] - 3391:11,
3399:8, 3399:9,
3457:22, 3457:25,
3579:17, 3580:4
90,000 [2] - 3494:10,
3494:14
91 [1] - 3522:2
917.951.5672 [1] -
3375:24
94 [1] - 3565:14
948-5711 [1] -
3376:21
95 [1] - 3457:24

973 [2] - 3376:6,
3377:5
9:30 [1] - 3642:4
9th [1] - 3376:10
a.m [2] - 3408:25,
3409:1
A4 [1] - 3519:21
Aachen [19] -
3380:3, 3381:1,
3381:10, 3382:1,
3382:3, 3385:5,
3388:20, 3389:16,
3391:15, 3393:9,
3393:12, 3394:1,
3425:25, 3430:10,
3439:20, 3479:19,
3494:5, 3559:13,
3560:5
abdomen [9] -
3380:16, 3506:15,
3520:7, 3526:3,
3526:16, 3630:3,
3631:18, 3632:18,
3635:4
abdominal [46] -
3380:17, 3383:4,
3383:5, 3385:18,
3390:8, 3390:24,
3392:5, 3397:6,
3397:24, 3403:10,
3403:19, 3404:22,
3405:5, 3421:11,
3433:15, 3433:19,
3441:15, 3461:9,
3461:19, 3488:10,
3520:1, 3522:16,
3523:9, 3524:5,
3526:4, 3526:8,
3527:2, 3528:18,
3532:9, 3538:17,
3545:18, 3575:11,
3575:25, 3589:16,
3590:18, 3628:22,
3629:3, 3630:11,
3630:13, 3630:20,
3632:2, 3632:12,
3633:6, 3633:13,
3633:25, 3634:23
ability [2] - 3417:1,
3643:11
able [19] - 3383:14,
3384:15, 3384:16,
3390:11, 3390:13,
3414:19, 3421:1,
3421:13, 3426:11,
3427:8, 3460:7,
3467:18, 3506:16,
3526:6, 3546:10,
3548:23, 3617:5,
3617:7, 3626:23

<p>absolute [1] - 3443:2</p> <p>absolutely [9] - 3417:12, 3423:5, 3426:13, 3451:9, 3601:2, 3607:5, 3631:11, 3634:10, 3634:12</p> <p>absorbed [1] - 3613:8</p> <p>abstract [8] - 3509:17, 3516:20, 3564:14, 3568:2, 3578:23, 3579:1, 3587:12, 3626:20</p> <p>academic [2] - 3383:9, 3385:1</p> <p>accept [2] - 3384:7, 3384:24</p> <p>accepted [8] - 3401:25, 3460:12, 3481:7, 3482:25, 3522:19, 3596:3, 3605:8, 3623:5</p> <p>access [3] - 3425:9, 3425:10, 3425:13</p> <p>accommodate [1] - 3553:23</p> <p>according [7] - 3427:23, 3475:3, 3510:14, 3510:16, 3580:4, 3615:6, 3639:18</p> <p>account [1] - 3472:3</p> <p>accurate [4] - 3468:6, 3469:15, 3469:17, 3643:9</p> <p>accustomed [1] - 3557:2</p> <p>achieve [3] - 3385:12, 3387:1, 3617:5</p> <p>achieved [1] - 3581:18</p> <p>acknowledgment [1] - 3563:8</p> <p>activities [6] - 3391:20, 3391:22, 3507:7, 3570:16, 3638:21, 3639:9</p> <p>acute [3] - 3444:16, 3444:19, 3622:22</p> <p>ADAM [1] - 3376:4</p> <p>adapt [2] - 3420:20, 3433:12</p> <p>adapted [2] - 3421:2, 3490:15</p> <p>add [1] - 3450:24</p> <p>added [3] - 3427:14, 3546:11, 3610:19</p> <p>adding [1] - 3453:12</p>	<p>addition [3] - 3387:10, 3392:5, 3392:10</p> <p>additional [1] - 3612:10</p> <p>address [1] - 3479:20</p> <p>adequate [3] - 3458:12, 3490:24, 3628:14</p> <p>adherence [1] - 3416:20</p> <p>adhesion [1] - 3566:18</p> <p>adhesions [1] - 3532:23</p> <p>adjourned [1] - 3642:8</p> <p>adjusted [1] - 3597:4</p> <p>Adler [2] - 3504:22, 3504:25</p> <p>Administrator [1] - 3643:5</p> <p>admission [5] - 3430:14, 3431:11, 3432:9, 3451:1, 3592:3</p> <p>admit [2] - 3562:3, 3618:7</p> <p>admitted [2] - 3408:14, 3411:11</p> <p>adopt [1] - 3433:6</p> <p>adopted [1] - 3460:15</p> <p>advanced [1] - 3390:13</p> <p>advantage [4] - 3381:6, 3397:10, 3427:17, 3472:25</p> <p>advantages [3] - 3425:8, 3503:21, 3602:18</p> <p>advice [3] - 3434:5, 3434:6, 3624:10</p> <p>affairs [2] - 3413:25, 3635:3</p> <p>affects [1] - 3412:11</p> <p>afternoon [2] - 3492:25, 3493:1</p> <p>afterwards [3] - 3381:18, 3381:20, 3383:17</p> <p>age [2] - 3517:1, 3534:9</p> <p>ago [6] - 3423:6, 3452:10, 3465:25, 3484:10, 3632:17, 3637:25</p> <p>agree [15] - 3405:20, 3406:20, 3521:16,</p>	<p>3522:5, 3522:12, 3527:14, 3546:19, 3622:25, 3626:9, 3627:14, 3629:24, 3630:1, 3635:5, 3635:15, 3635:23</p> <p>agreed [4] - 3418:3, 3534:17, 3598:25, 3599:25</p> <p>agreeing [1] - 3599:22</p> <p>agreement [2] - 3482:14, 3634:23</p> <p>ahead [8] - 3421:20, 3422:24, 3446:11, 3513:1, 3519:9, 3541:18, 3629:2, 3638:7</p> <p>aim [1] - 3581:18</p> <p>al [2] - 3592:9, 3592:17</p> <p>algorithm [1] - 3473:3</p> <p>allow [16] - 3407:16, 3419:6, 3431:18, 3431:24, 3432:8, 3448:11, 3471:11, 3478:25, 3594:3, 3595:15, 3627:2, 3629:17, 3631:14, 3633:7, 3634:4, 3634:6</p> <p>allowed [10] - 3382:14, 3383:17, 3383:24, 3384:1, 3390:19, 3401:8, 3507:23, 3600:9, 3626:13, 3626:25</p> <p>allowing [2] - 3554:1, 3640:19</p> <p>allows [1] - 3553:22</p> <p>almost [12] - 3385:3, 3451:22, 3451:23, 3453:9, 3455:6, 3461:6, 3482:11, 3543:2, 3578:6, 3613:18, 3632:19, 3633:5</p> <p>alone [2] - 3462:1, 3529:2</p> <p>alternatives [1] - 3611:8</p> <p>Altman [1] - 3582:23</p> <p>altogether [1] - 3446:20</p> <p>America [1] - 3499:9</p> <p>Amid [11] - 3457:11, 3574:11, 3574:13, 3574:14, 3574:16, 3590:8, 3590:11,</p>	<p>3590:15, 3603:3, 3608:15</p> <p>Amid's [2] - 3603:10, 3608:17</p> <p>amount [25] - 3388:25, 3405:22, 3421:12, 3421:14, 3422:5, 3422:19, 3442:16, 3443:22, 3443:24, 3445:6, 3445:7, 3445:9, 3445:10, 3456:22, 3466:6, 3470:10, 3477:10, 3477:12, 3483:25, 3484:3, 3518:17, 3519:13, 3520:11, 3520:24, 3569:1</p> <p>amounts [2] - 3474:13, 3474:15</p> <p>analgesic [2] - 3570:15, 3638:19</p> <p>analyses [1] - 3595:22</p> <p>analysis [7] - 3395:6, 3396:4, 3464:14, 3473:4, 3534:9, 3583:22, 3587:1</p> <p>analyze [3] - 3387:21, 3395:22, 3397:8</p> <p>analyzed [1] - 3412:10</p> <p>analyzing [2] - 3410:10, 3621:6</p> <p>anatomical [3] - 3537:9, 3537:13, 3539:2</p> <p>anchor [2] - 3594:4, 3595:16</p> <p>and.. [1] - 3602:7</p> <p>Anderson [2] - 3547:11, 3638:1</p> <p>ANDERSON [99] - 3376:9, 3376:9, 3379:8, 3379:21, 3386:17, 3386:23, 3386:24, 3394:16, 3394:21, 3405:3, 3405:12, 3405:16, 3407:14, 3407:21, 3407:24, 3408:11, 3420:6, 3420:7, 3422:25, 3427:4, 3427:5, 3430:14, 3431:11, 3432:14, 3437:24, 3438:4, 3438:5, 3438:11, 3438:12, 3449:23, 3450:2, 3450:10,</p>	<p>3451:9, 3451:13, 3451:17, 3452:7, 3452:15, 3452:16, 3464:24, 3471:13, 3477:25, 3483:22, 3483:23, 3486:7, 3486:13, 3486:16, 3486:20, 3487:17, 3489:5, 3489:11, 3492:4, 3527:20, 3527:25, 3530:10, 3537:15, 3537:19, 3538:10, 3539:6, 3597:10, 3600:10, 3600:19, 3601:14, 3602:12, 3602:13, 3603:12, 3603:13, 3603:23, 3604:1, 3604:2, 3607:18, 3607:20, 3609:11, 3618:14, 3618:17, 3620:15, 3625:10, 3626:14, 3626:18, 3627:6, 3627:10, 3628:2, 3628:5, 3629:1, 3629:15, 3629:18, 3631:5, 3631:11, 3631:15, 3631:16, 3633:9, 3633:11, 3635:9, 3635:13, 3635:14, 3635:20, 3635:22, 3635:25, 3640:17, 3641:16</p> <p>Angeles [1] - 3457:11</p> <p>angiogenesis [1] - 3592:7</p> <p>animal [1] - 3570:8</p> <p>animals [3] - 3565:22, 3568:5, 3568:17</p> <p>Anju [1] - 3582:23</p> <p>ANN [3] - 3375:23, 3643:4, 3643:15</p> <p>announced [1] - 3571:18</p> <p>answer [9] - 3471:11, 3472:12, 3474:6, 3489:4, 3507:24, 3508:15, 3620:13, 3628:25, 3641:18</p> <p>answers [2] - 3412:18, 3543:13</p> <p>anterior [12] - 3509:9, 3509:12, 3509:19, 3509:23, 3510:13, 3510:24, 3511:10, 3512:3,</p>
--	--	---	--	--

3512:8, 3516:17,
3516:23, 3536:10
apart [1] - 3447:5
apologize [1] -
3543:13
appear [4] - 3477:19,
3627:4, 3637:9,
3640:11
appearance [3] -
3487:11, 3489:16,
3577:21
APPEARANCES [2] -
3376:1, 3377:1
application [2] -
3490:7, 3507:16
applied [8] -
3473:22, 3474:19,
3475:11, 3476:3,
3476:9, 3484:6,
3599:13, 3617:20
apply [10] - 3383:24,
3384:22, 3401:23,
3402:2, 3461:12,
3474:17, 3476:6,
3482:12, 3539:21,
3615:2
appointed [2] -
3402:25, 3403:6
approach [11] -
3405:17, 3430:15,
3430:20, 3430:22,
3485:24, 3527:21,
3537:16, 3600:3,
3607:18, 3618:14,
3626:15
appropriate [7] -
3414:8, 3431:3,
3436:12, 3443:3,
3466:9, 3522:6,
3627:5
appropriately [1] -
3443:9
April [1] - 3596:3
Archives [1] - 3564:3
area [47] - 3380:3,
3381:12, 3404:21,
3424:13, 3427:1,
3429:7, 3429:8,
3433:13, 3440:12,
3446:17, 3455:15,
3455:18, 3456:18,
3461:19, 3463:1,
3463:2, 3463:3,
3463:9, 3463:10,
3463:19, 3468:3,
3469:14, 3470:7,
3472:7, 3476:8,
3476:11, 3477:16,
3478:8, 3490:22,
3490:25, 3522:15,

3529:11, 3575:12,
3584:19, 3610:2,
3610:23, 3614:15,
3617:20, 3631:1,
3633:2, 3633:16,
3640:21, 3640:22,
3640:24
areas [6] - 3414:7,
3455:10, 3472:22,
3522:19, 3528:3,
3630:20
argue [1] - 3409:3
argued [2] - 3411:10,
3417:10
argument [1] -
3409:5
argumentative [2] -
3625:8, 3628:1
arm [4] - 3454:7,
3474:12, 3476:5
arms [26] - 3435:10,
3471:1, 3475:12,
3476:21, 3478:4,
3485:2, 3485:8,
3485:13, 3486:3,
3487:1, 3487:10,
3487:14, 3487:19,
3488:23, 3489:6,
3489:8, 3489:9,
3489:13, 3489:18,
3616:12, 3616:14,
3616:15, 3616:17,
3616:19, 3625:5,
3632:5
Arnaud [2] -
3484:11, 3484:18
article [103] -
3425:20, 3425:22,
3479:14, 3479:17,
3480:2, 3480:20,
3499:5, 3499:12,
3500:2, 3501:15,
3505:21, 3508:5,
3508:6, 3508:9,
3509:7, 3510:3,
3510:15, 3510:16,
3511:6, 3511:15,
3511:17, 3512:19,
3515:11, 3515:16,
3516:14, 3534:23,
3540:6, 3540:8,
3545:13, 3549:12,
3552:5, 3552:7,
3552:10, 3555:2,
3563:3, 3563:4,
3563:10, 3566:12,
3567:1, 3567:10,
3567:12, 3567:21,
3567:22, 3569:5,
3569:7, 3569:25,

3570:23, 3571:5,
3571:10, 3575:4,
3577:23, 3578:3,
3578:15, 3579:3,
3582:2, 3586:1,
3586:16, 3586:18,
3587:12, 3587:25,
3588:2, 3588:10,
3589:14, 3590:1,
3590:16, 3592:10,
3592:15, 3592:22,
3592:25, 3594:10,
3594:18, 3594:23,
3594:24, 3595:21,
3599:1, 3599:11,
3603:14, 3606:10,
3607:10, 3607:13,
3609:16, 3612:4,
3622:14, 3622:17,
3623:7, 3625:19,
3631:5, 3631:6,
3637:2, 3637:11,
3637:12, 3637:16,
3637:19, 3637:20,
3638:11, 3638:16,
3639:16, 3640:5,
3640:11, 3641:4
articles [13] -
3404:20, 3409:13,
3420:10, 3420:15,
3595:1, 3607:24,
3620:17, 3620:19,
3620:23, 3627:18,
3639:2, 3639:4,
3639:11
articulate [1] -
3545:23
aside [1] - 3411:4
aslater@mskf.net
[1] - 3376:7
aspect [4] - 3527:1,
3546:9, 3555:12,
3621:21
aspects [2] -
3412:14, 3425:21
assessed [1] -
3583:20
assesses [1] -
3509:18
assessment [1] -
3467:6
assign [2] - 3561:6,
3561:8
assistant [2] -
3389:25, 3390:2
associated [4] -
3424:19, 3550:3,
3570:14, 3638:18
assume [3] - 3428:2,
3463:4, 3579:8

assuming [3] -
3415:25, 3486:2,
3573:16
assumption [1] -
3597:2
ATL-L-6966-10 [1] -
3375:2
ATLANTIC [2] -
3375:1, 3375:9
Atlantic [1] - 3375:10
atoms [1] - 3610:19
Atrium [3] - 3531:3,
3591:10, 3591:11
attempted [1] -
3622:12
attendant [1] -
3381:21
attending [1] -
3382:15
attention [4] -
3416:7, 3420:16,
3432:19, 3453:25
attorney [1] -
3507:25
attract [1] - 3383:14
attracting [2] -
3381:12, 3444:12
audience [1] -
3400:9
August [1] - 3482:9
Austria [1] - 3384:13
author [10] -
3535:20, 3535:25,
3577:23, 3593:2,
3595:25, 3637:11,
3637:16, 3637:18,
3641:4, 3641:5
author's [1] -
3549:25
authored [2] -
3582:21, 3590:8
authors [10] -
3398:3, 3545:5,
3556:2, 3567:22,
3582:25, 3594:20,
3594:24, 3600:23,
3639:22, 3640:4
automated [2] -
3472:21, 3473:17
automatic [1] -
3464:14
automatically [2] -
3473:1, 3473:4
available [7] -
3384:13, 3415:13,
3473:12, 3507:18,
3517:8, 3517:19,
3621:6
Avenue [1] - 3377:4
average [2] -

3536:17, 3536:18
average/mean [1] -
3536:19
avoid [9] - 3433:9,
3438:19, 3447:10,
3457:4, 3457:5,
3530:5, 3596:23,
3622:9
avoidance [1] -
3564:22
avoided [2] -
3426:17, 3622:8
award [1] - 3562:22
aware [21] - 3383:2,
3385:19, 3425:5,
3425:6, 3429:12,
3438:14, 3444:13,
3447:16, 3459:11,
3460:9, 3477:20,
3479:14, 3480:25,
3482:8, 3501:18,
3502:15, 3502:21,
3525:8, 3537:12,
3603:6, 3636:15
Axel [2] - 3484:11,
3484:18
Bacharach [1] -
3375:9
background [4] -
3380:23, 3388:7,
3404:2, 3522:21
bacteria [1] - 3606:1
bad [13] - 3422:21,
3442:12, 3442:19,
3450:23, 3458:11,
3470:15, 3546:8,
3547:1, 3547:2,
3606:18, 3612:12,
3621:22, 3638:23
bag [1] - 3490:8
bailliff [1] - 3407:16
balance [1] -
3534:10
bar [3] - 3618:19,
3636:22, 3637:6
Bard [1] - 3505:7
bars [8] - 3456:8,
3468:19, 3613:15,
3617:11, 3617:21,
3617:24, 3618:23,
3619:1
base [1] - 3518:7
based [15] - 3419:4,
3447:7, 3457:13,
3461:2, 3461:23,
3470:10, 3472:4,
3491:3, 3497:3,
3505:4, 3529:14,
3583:22, 3595:22,
3633:8

<p>basic [5] - 3381:14, 3421:8, 3424:3, 3457:21, 3569:22</p> <p>basis [4] - 3428:22, 3430:19, 3431:1, 3450:9</p> <p>bears [1] - 3472:19</p> <p>became [8] - 3381:18, 3381:20, 3382:17, 3388:19, 3389:15, 3390:7, 3438:13, 3552:22</p> <p>become [2] - 3461:16, 3633:22</p> <p>becoming [5] - 3382:12, 3382:19, 3382:23, 3448:15</p> <p>began [1] - 3394:4</p> <p>begin [3] - 3382:17, 3407:14, 3455:24</p> <p>beginning [15] - 3382:24, 3383:1, 3393:20, 3432:5, 3451:1, 3498:4, 3498:17, 3504:4, 3504:19, 3507:12, 3542:17, 3547:6, 3568:23, 3578:24, 3595:11</p> <p>begins [2] - 3581:13, 3596:7</p> <p>begun [1] - 3394:6</p> <p>behavior [1] - 3442:15</p> <p>behind [1] - 3595:5</p> <p>beings [1] - 3602:2</p> <p>Belgium [8] - 3380:2, 3380:4, 3380:7, 3381:13, 3552:14, 3593:6, 3593:10, 3593:18</p> <p>believes [2] - 3484:18, 3625:3</p> <p>below [3] - 3439:16, 3475:12, 3478:14</p> <p>Ben [1] - 3518:18</p> <p>ben@andersonlawoffices.net [1] - 3376:12</p> <p>bend [1] - 3615:21</p> <p>bending [1] - 3461:11</p> <p>benefit [1] - 3410:8</p> <p>benefits [8] - 3410:11, 3410:18, 3414:18, 3414:20, 3416:2, 3419:3, 3507:6, 3534:5</p> <p>benign [1] - 3585:10</p> <p>BENJAMIN [1] -</p>	<p>3376:9</p> <p>Berlin [2] - 3564:12, 3564:13</p> <p>BERNSTEIN [1] - 3376:14</p> <p>Berthier [1] - 3435:13</p> <p>best [19] - 3395:25, 3500:23, 3501:1, 3522:15, 3522:18, 3537:13, 3558:9, 3558:13, 3560:7, 3571:19, 3596:23, 3597:2, 3612:11, 3621:24, 3622:1, 3622:8, 3624:10, 3639:9, 3643:10</p> <p>better [24] - 3387:25, 3389:1, 3403:22, 3403:23, 3422:22, 3427:1, 3427:10, 3431:20, 3439:6, 3442:16, 3451:24, 3456:2, 3460:11, 3475:17, 3481:9, 3481:14, 3536:21, 3549:11, 3566:2, 3566:4, 3581:8, 3597:17, 3598:4, 3621:17</p> <p>between [34] - 3385:10, 3391:13, 3392:4, 3393:9, 3393:17, 3395:25, 3401:3, 3406:17, 3422:18, 3423:21, 3425:24, 3445:1, 3445:7, 3446:15, 3446:22, 3446:23, 3446:25, 3447:13, 3453:4, 3454:16, 3455:3, 3463:25, 3467:16, 3468:19, 3473:17, 3486:5, 3528:24, 3566:8, 3588:6, 3595:1, 3601:24, 3630:11, 3632:4</p> <p>beyond [8] - 3413:4, 3415:23, 3418:7, 3459:17, 3474:20, 3528:1, 3537:23, 3629:13</p> <p>bidirectional [1] - 3554:1</p> <p>big [22] - 3381:6, 3397:10, 3402:1, 3458:15, 3473:2, 3519:8, 3519:18, 3519:20, 3537:12,</p>	<p>3541:23, 3546:3, 3554:7, 3563:3, 3589:23, 3589:24, 3590:1, 3590:2, 3618:5, 3619:20, 3619:23, 3632:16, 3634:21</p> <p>bigger [11] - 3430:22, 3445:11, 3445:12, 3445:13, 3519:22, 3519:23, 3519:24, 3520:1, 3606:4, 3626:24</p> <p>biggest [3] - 3381:5, 3381:11, 3519:19</p> <p>Billerica [1] - 3505:7</p> <p>bindings [1] - 3458:17</p> <p>biochemistry [1] - 3383:12</p> <p>biocompatibility [30] - 3545:18, 3545:21, 3546:4, 3546:8, 3546:16, 3546:19, 3546:22, 3546:23, 3547:2, 3547:15, 3547:18, 3548:16, 3564:16, 3564:18, 3566:15, 3566:17, 3569:2, 3571:19, 3571:21, 3578:7, 3585:21, 3587:21, 3621:2, 3621:7, 3639:1, 3639:8, 3639:10, 3639:18, 3639:22</p> <p>biocompatible [1] - 3546:20</p> <p>biodegradable [2] - 3592:20, 3593:11</p> <p>Biological [1] - 3440:11</p> <p>biology [1] - 3595:5</p> <p>biomaterial [13] - 3380:17, 3382:9, 3385:15, 3387:10, 3391:6, 3391:22, 3392:8, 3394:25, 3396:15, 3397:4, 3405:5, 3408:1, 3486:7</p> <p>biomaterials [10] - 3398:16, 3399:6, 3401:12, 3402:14, 3404:24, 3491:6, 3538:16, 3578:7, 3589:15, 3590:16</p> <p>biomechanical [2] - 3456:5, 3480:17</p> <p>biomedical [1] -</p>	<p>3391:4</p> <p>biopsied [1] - 3585:3</p> <p>biopsy [6] - 3583:17, 3584:10, 3584:16, 3584:18, 3585:1, 3639:16</p> <p>Birkenhauer [1] - 3607:22</p> <p>bit [32] - 3380:22, 3384:12, 3385:24, 3386:17, 3387:25, 3388:1, 3389:1, 3389:7, 3391:17, 3392:3, 3394:24, 3395:3, 3401:3, 3423:22, 3440:10, 3462:9, 3512:5, 3516:7, 3519:11, 3520:21, 3523:16, 3528:14, 3555:15, 3566:4, 3569:17, 3583:25, 3590:7, 3590:14, 3599:19, 3610:20, 3611:6, 3628:8</p> <p>black [2] - 3454:14, 3467:17</p> <p>black/white [1] - 3454:13</p> <p>bladder [2] - 3517:3, 3518:7</p> <p>blind [1] - 3506:15</p> <p>block [2] - 3535:15, 3570:11</p> <p>Blomgren [1] - 3582:22</p> <p>blood [8] - 3383:13, 3526:9, 3588:15, 3588:16, 3592:7, 3605:8, 3605:11, 3605:25</p> <p>Bo [1] - 3582:22</p> <p>board [4] - 3384:6, 3384:23, 3384:24, 3594:11</p> <p>Bob [1] - 3469:11</p> <p>Bobyn [2] - 3592:9, 3592:11</p> <p>bodies [9] - 3387:18, 3391:24, 3444:5, 3444:24, 3445:15, 3445:22, 3520:12, 3584:3, 3584:7</p> <p>body [68] - 3385:16, 3395:2, 3395:6, 3397:2, 3400:20, 3402:16, 3405:1, 3405:7, 3420:12, 3423:14, 3423:18, 3426:9, 3427:2,</p>	<p>3441:9, 3441:20, 3441:22, 3441:25, 3444:2, 3444:7, 3444:9, 3444:10, 3444:12, 3444:17, 3444:20, 3444:22, 3445:2, 3445:4, 3445:8, 3445:10, 3445:11, 3445:20, 3454:19, 3454:20, 3454:24, 3464:5, 3465:3, 3477:14, 3478:25, 3485:4, 3490:25, 3495:10, 3513:14, 3514:13, 3525:5, 3533:8, 3545:25, 3546:4, 3547:8, 3547:11, 3547:14, 3547:17, 3547:20, 3547:23, 3547:25, 3548:3, 3548:8, 3548:17, 3548:18, 3549:3, 3549:5, 3568:25, 3581:16, 3583:19, 3587:16, 3610:21, 3614:15, 3628:10, 3628:12</p> <p>body's [4] - 3387:19, 3388:14, 3396:19, 3605:25</p> <p>book [4] - 3398:10, 3398:12, 3398:19, 3398:20</p> <p>books [2] - 3398:10, 3398:19</p> <p>border [2] - 3445:1, 3445:7</p> <p>bottom [20] - 3411:8, 3484:4, 3499:14, 3510:22, 3536:19, 3536:24, 3545:8, 3547:5, 3555:19, 3556:7, 3564:8, 3570:25, 3578:4, 3579:23, 3579:24, 3581:13, 3582:8, 3587:25, 3595:10, 3614:1</p> <p>Boulevard [1] - 3375:9</p> <p>boundaries [1] - 3419:23</p> <p>bounds [1] - 3418:7</p> <p>bowel [1] - 3390:15</p> <p>bowels [2] - 3385:23, 3513:25</p> <p>braided [1] - 3553:5</p> <p>branch [1] - 3529:23</p> <p>branches [1] -</p>
---	--	--	--	--

3632:11
break [9] - 3408:9,
3408:10, 3408:23,
3420:10, 3486:15,
3492:6, 3554:8,
3554:11, 3583:24
bridge [1] - 3418:19
bridged [1] - 3470:18
bridging [28] -
3391:12, 3424:25,
3446:24, 3447:2,
3448:6, 3452:20,
3459:8, 3459:13,
3459:21, 3461:17,
3470:17, 3471:2,
3471:22, 3476:11,
3533:14, 3544:1,
3549:15, 3549:17,
3549:21, 3549:24,
3550:7, 3566:8,
3588:3, 3596:23,
3619:7, 3623:10,
3623:14, 3638:25
Bridging [1] -
3550:11
brief [3] - 3412:4,
3414:22, 3486:22
briefly [12] - 3388:21,
3390:8, 3391:3,
3395:5, 3395:8,
3401:20, 3420:20,
3421:22, 3424:2,
3444:4, 3486:11,
3549:16
Brigitte [8] - 3430:2,
3430:4, 3430:5,
3432:25, 3436:18,
3437:12, 3439:17,
3439:21
bring [18] - 3379:2,
3411:21, 3412:2,
3413:11, 3413:19,
3416:6, 3416:9,
3419:16, 3420:16,
3426:15, 3454:4,
3492:14, 3530:1,
3539:4, 3554:18,
3600:10, 3619:25,
3635:18
bringing [1] - 3455:8
brings [1] - 3619:1
brochure [2] -
3409:16, 3419:1
brochures [2] -
3409:15, 3412:25
brought [6] -
3421:23, 3425:25,
3426:4, 3426:8,
3432:19, 3630:12
Brussels [1] -

3399:25
bucks [1] - 3493:16
build [6] - 3389:1,
3445:1, 3544:3,
3597:17, 3597:21
building [1] -
3444:11
buildings [1] -
3381:11
builds [1] - 3533:15
built [1] - 3534:16
bullet [2] - 3614:1,
3633:10
bunching [4] -
3423:11, 3471:4,
3471:15, 3471:20
Burkley [6] - 3465:8,
3465:9, 3465:14,
3473:7, 3473:24,
3620:3
business [1] -
3395:19
busy [1] - 3517:16
but.. [1] - 3524:6
BUTLER [1] -
3376:18
buttocks [4] -
3485:9, 3488:25,
3624:24, 3631:24
buy [2] - 3460:1,
3561:19
BY [57] - 3376:3,
3376:4, 3376:9,
3376:14, 3376:19,
3376:19, 3377:3,
3379:21, 3386:24,
3394:21, 3405:16,
3407:24, 3420:7,
3422:25, 3427:5,
3432:14, 3437:24,
3438:5, 3438:12,
3449:23, 3451:17,
3452:16, 3464:24,
3471:13, 3477:25,
3483:23, 3486:20,
3487:17, 3489:11,
3492:24, 3508:3,
3519:12, 3530:14,
3539:10, 3554:25,
3597:10, 3601:14,
3602:13, 3603:13,
3604:2, 3607:20,
3609:11, 3618:17,
3620:15, 3625:10,
3627:10, 3628:5,
3629:1, 3629:18,
3631:16, 3633:11,
3635:14, 3635:22,
3636:4, 3638:8,
3640:9, 3640:17

calculate [4] -
3463:5, 3463:19,
3494:20, 3585:18
calculating [1] -
3475:21
calculation [2] -
3463:10, 3596:16
calculations [2] -
3440:16, 3520:17
cameras [1] -
3557:18
CANNADA [1] -
3376:18
cannot [9] - 3397:11,
3477:16, 3524:3,
3546:15, 3547:22,
3577:17, 3577:20,
3582:1, 3593:22
cannula [1] -
3484:19
cannulas [1] -
3496:22
capsule [1] -
3446:13
carbon [1] - 3502:18
care [5] - 3389:16,
3389:19, 3389:23,
3447:12
career [5] - 3383:8,
3383:9, 3385:1,
3394:20, 3491:5
careful [1] - 3534:7
CAROL [1] - 3375:16
Carolyn [1] - 3582:22
carried [2] - 3509:21,
3532:15
carries [1] - 3533:1
case [24] - 3380:21,
3391:24, 3398:16,
3399:5, 3405:18,
3405:24, 3406:24,
3407:23, 3408:16,
3412:1, 3433:5,
3436:1, 3436:6,
3453:14, 3477:18,
3491:9, 3493:8,
3493:18, 3494:17,
3530:4, 3538:21,
3565:2, 3565:14,
3622:22
cases [4] - 3435:11,
3504:7, 3600:8,
3630:23
categorized [1] -
3598:6
causation [1] -
3416:21
causes [1] - 3533:17
causing [1] - 3471:5
cavity [2] - 3532:9,

3575:25
CCR [3] - 3375:23,
3643:4, 3643:15
CCR-RDR-CRR [1] -
3643:15
cell [1] - 3566:3
cells [17] - 3383:13,
3424:4, 3444:11,
3444:13, 3444:21,
3445:5, 3454:20,
3462:25, 3488:3,
3604:3, 3604:5,
3604:7, 3605:3,
3605:11, 3606:1,
3606:3
cellular [1] - 3395:13
Center [3] - 3564:7,
3564:10, 3593:4
center [4] - 3449:12,
3499:23, 3569:21,
3638:12
centers [1] - 3381:3
centimeter [2] -
3474:21, 3616:18
centimeters [1] -
3633:15
centric [1] - 3614:9
century [1] - 3500:14
certain [8] - 3381:24,
3475:2, 3514:12,
3532:16, 3565:12,
3593:19, 3624:8,
3634:9
certainly [19] -
3386:23, 3410:8,
3411:3, 3412:1,
3412:8, 3412:17,
3414:19, 3432:1,
3433:3, 3487:21,
3487:23, 3495:2,
3496:9, 3525:3,
3530:1, 3530:10,
3538:23, 3592:22,
3626:14
certifications [1] -
3392:7
Certified [2] -
3643:6, 3643:16
certify [1] - 3643:7
cetera [2] - 3450:8,
3594:16
chairmen [1] -
3390:3
challenge [4] -
3467:4, 3474:1,
3474:2, 3634:21
chance [6] -
3428:15, 3485:13,
3538:14, 3572:10,
3612:6, 3641:10

change [4] -
3386:10, 3391:25,
3413:17, 3504:12
changed [3] -
3418:18, 3453:18,
3459:19
changes [6] -
3420:24, 3450:11,
3455:20, 3455:21,
3493:14, 3493:15
changing [3] -
3413:14, 3455:18,
3522:17
channel [2] -
3543:18, 3623:23
channels [1] -
3632:11
chapters [4] -
3398:11, 3398:12,
3398:19, 3398:20
characteristics [2] -
3566:18, 3580:9
characterization [1]
- 3479:19
charge [3] - 3389:3,
3389:12, 3465:10
Charlotte [1] -
3415:10
chart [2] - 3586:4,
3608:16
check [1] - 3563:7
checking [1] -
3536:14
Chinese [1] -
3524:21
choice [2] - 3527:12,
3634:24
choose [1] - 3604:6
chose [5] - 3412:19,
3474:14, 3483:8,
3483:13, 3626:25
Christian [1] -
3582:22
CHRISTY [1] -
3376:19
christy.jones@
butlersnow.com [1] -
3376:22
chronic [12] -
3423:24, 3426:10,
3444:22, 3532:21,
3533:9, 3533:21,
3551:1, 3551:16,
3564:22, 3566:16,
3622:23
Chronic [1] -
3550:20
Ciarrocca [6] -
3434:24, 3435:4,
3465:8, 3465:14,

3465:23, 3469:12
circle [1] - 3446:4
circulated [1] - 3446:21
citations [1] - 3460:12
cited [2] - 3398:3, 3398:7
City [1] - 3375:10
claim [1] - 3534:20
claimed [1] - 3561:23
clarification [1] - 3417:15
clarify [1] - 3423:1
class [2] - 3543:22, 3624:4
classical [1] - 3625:15
classification [13] - 3457:13, 3458:22, 3459:15, 3459:21, 3574:13, 3574:17, 3595:21, 3597:13, 3598:10, 3599:23, 3608:16, 3608:17, 3608:23
Classification [1] - 3589:15
classify [2] - 3598:18, 3624:8
classifying [2] - 3458:23, 3590:16
clear [16] - 3412:4, 3422:10, 3445:11, 3449:15, 3458:14, 3481:25, 3482:24, 3483:4, 3490:20, 3494:22, 3543:6, 3547:7, 3549:1, 3602:17, 3603:18, 3603:20
clearly [10] - 3420:14, 3445:14, 3478:19, 3481:6, 3507:17, 3548:20, 3599:14, 3631:1, 3631:10
CLERK [2] - 3379:14, 3642:3
Cleveland [1] - 3376:11
clinic [1] - 3500:22
Clinical [1] - 3583:2
clinical [18] - 3427:15, 3442:14, 3442:15, 3449:7, 3456:7, 3503:19, 3538:19, 3569:10, 3569:22, 3585:20,

3597:19, 3598:2, 3621:19, 3621:22, 3626:1, 3626:6, 3627:23, 3638:12
Clinics [1] - 3499:8
clip [2] - 3485:22, 3486:22
close [9] - 3380:3, 3393:6, 3393:19, 3420:15, 3446:18, 3513:15, 3513:22, 3553:18, 3594:9
closely [2] - 3480:13, 3550:3
closer [1] - 3453:3
co [3] - 3545:5, 3594:24, 3637:18
co-author [1] - 3637:18
co-authors [2] - 3545:5, 3594:24
coated [2] - 3569:11, 3569:24
coating [1] - 3621:7
collaboration [3] - 3393:6, 3393:9, 3393:19
collagen [3] - 3570:1, 3592:8, 3602:7
collagen-polyester [1] - 3570:1
collagens [1] - 3566:5
collapse [4] - 3429:3, 3455:24, 3616:11, 3618:4
colleague [3] - 3395:16, 3440:2, 3454:5
colleagues [5] - 3393:15, 3426:15, 3439:19, 3534:17, 3600:13
collect [5] - 3384:4, 3384:5, 3384:20, 3384:21, 3601:21
collected [1] - 3448:21
collective [1] - 3504:7
Collier [1] - 3505:22
Cologne [1] - 3623:2
Colony [1] - 3376:20
colporrhaphy [8] - 3496:6, 3509:9, 3509:12, 3509:19, 3509:23, 3510:13, 3510:24, 3511:11
column [1] - 3550:17

combination [2] - 3583:20, 3604:16
combine [1] - 3397:10
combined [2] - 3546:11, 3585:19
comfortable [2] - 3475:6, 3599:19
coming [20] - 3380:5, 3403:11, 3403:17, 3407:7, 3413:15, 3445:6, 3446:3, 3446:8, 3448:15, 3470:1, 3487:2, 3487:4, 3488:3, 3522:24, 3533:6, 3536:13, 3548:5, 3553:18, 3577:19, 3622:6
comment [2] - 3507:23, 3513:12
commenters [1] - 3600:23
common [2] - 3579:12, 3634:23
commonly [2] - 3523:7, 3552:23
community [4] - 3394:6, 3398:4, 3425:9, 3459:11
company [17] - 3409:19, 3413:13, 3413:18, 3413:24, 3414:9, 3416:10, 3416:16, 3417:4, 3418:14, 3419:5, 3419:12, 3419:13, 3419:15, 3450:8, 3450:13, 3559:10, 3562:2
comparable [1] - 3566:15
comparative [1] - 3538:20
comparatively [1] - 3489:23
compare [3] - 3465:19, 3467:7, 3573:13
compared [5] - 3571:21, 3578:6, 3579:12, 3594:17, 3594:20
comparing [2] - 3569:10, 3621:14
comparison [5] - 3421:10, 3457:16, 3563:21, 3611:3, 3611:25
Comparison [1] -

3563:11
compensated [1] - 3407:12
competitive [1] - 3467:6
competitors [1] - 3465:19
complaints [2] - 3551:7, 3622:4
complete [2] - 3429:3, 3476:11
completed [1] - 3497:11
completely [13] - 3386:7, 3455:2, 3476:7, 3478:13, 3485:15, 3520:3, 3524:21, 3548:8, 3587:7, 3615:8, 3629:3, 3630:15, 3640:6
complex [1] - 3525:19
compliance [1] - 3643:8
complicated [1] - 3505:2
complication [1] - 3451:5
complications [21] - 3385:20, 3397:1, 3413:24, 3414:1, 3414:19, 3415:22, 3416:2, 3417:11, 3417:12, 3425:2, 3443:13, 3443:18, 3448:7, 3456:1, 3479:9, 3535:11, 3581:10, 3589:16, 3590:17, 3619:13, 3626:2
component [1] - 3424:7
components [1] - 3566:3
composite [3] - 3569:12, 3570:1, 3570:17
comprehensive [2] - 3392:21, 3394:10
compressed [1] - 3643:10
computer [2] - 3473:23, 3557:18
computerized [1] - 3583:21
concept [10] - 3425:17, 3425:21, 3425:23, 3460:2, 3464:18, 3482:8,

3482:24, 3544:24, 3609:5, 3623:7
conception [2] - 3420:22, 3607:6
concepts [1] - 3548:18
concern [8] - 3416:3, 3418:20, 3421:25, 3435:22, 3485:1, 3485:17, 3488:12
concerned [2] - 3385:25, 3590:15
concession [1] - 3418:3
concluded [1] - 3639:22
conclusion [4] - 3566:12, 3566:13, 3581:3, 3638:17
Conclusion [2] - 3518:5, 3586:22
conclusions [1] - 3581:14
Conclusions [2] - 3570:11, 3570:12
condition [2] - 3525:24, 3526:8
conditions [1] - 3612:16
conduct [1] - 3450:23
conference [1] - 3399:22
conferences [9] - 3398:23, 3399:13, 3399:19, 3400:9, 3400:11, 3400:13, 3400:15, 3527:3, 3534:12
confess [1] - 3525:16
configuration [7] - 3441:17, 3442:3, 3453:20, 3478:18, 3488:14, 3553:2, 3630:17
confined [2] - 3417:25, 3418:13
confirm [5] - 3602:9, 3602:14, 3602:22, 3602:23, 3627:23
confirmation [1] - 3623:17
confirmed [4] - 3427:16, 3453:12, 3453:17, 3602:25
confirms [1] - 3518:6
conflict [1] - 3623:2
conflicting [1] - 3625:16

congratulations [1] - 3603:7 conjunction [1] - 3509:19 connective [3] - 3569:1, 3599:15, 3602:19 consecutive [2] - 3505:24, 3585:7 consequence [2] - 3424:11, 3551:16 consequences [3] - 3456:4, 3456:25, 3579:13 consider [1] - 3497:2 considerable [2] - 3552:25, 3633:21 considerate [1] - 3404:9 considered [4] - 3459:17, 3469:15, 3501:10, 3547:16 considers [1] - 3596:22 constructed [1] - 3636:13 construction [7] - 3466:20, 3467:3, 3469:16, 3522:7, 3522:9, 3553:22, 3617:14 constructions [2] - 3433:8, 3521:19 consultant [13] - 3431:13, 3431:14, 3432:6, 3432:17, 3437:8, 3440:5, 3559:17, 3560:14, 3560:17, 3560:19, 3560:24, 3562:5, 3563:5 consultants [2] - 3439:3, 3439:4 consulting [2] - 3392:16, 3394:4 consumers [1] - 3401:23 consumption [2] - 3570:16, 3638:20 cont.'d [1] - 3377:1 contacted [1] - 3437:17 contain [4] - 3525:6, 3540:17, 3591:14, 3592:1 content [3] - 3482:21, 3508:17, 3561:7 contents [1] - 3436:7 context [1] - 3442:20	continue [5] - 3399:18, 3420:5, 3433:2, 3450:15, 3554:23 continued [1] - 3450:20 contracted [3] - 3448:14, 3630:2, 3630:4 contracting [1] - 3423:10 contraction [4] - 3423:9, 3449:14, 3471:16, 3622:7 contradiction [2] - 3460:10, 3482:21 contrast [2] - 3551:6, 3551:15 contributor [2] - 3561:10, 3562:1 control [2] - 3562:25, 3593:22 controlled [2] - 3569:21, 3638:11 controls [3] - 3583:16, 3584:5, 3585:9 conventional [1] - 3571:22 conversation [1] - 3439:22 conversion [1] - 3493:10 convert [1] - 3631:9 converted [1] - 3454:13 convinced [2] - 3474:22, 3476:24 cooperation [3] - 3391:2, 3391:5, 3598:9 coordinate [1] - 3391:20 coordinated [1] - 3389:1 copy [6] - 3453:18, 3500:1, 3541:1, 3555:1, 3571:5, 3572:5 corner [1] - 3589:4 corporate [6] - 3410:2, 3413:6, 3414:25, 3415:16, 3418:11, 3418:24 correct [468] - 3380:9, 3385:17, 3388:17, 3389:13, 3389:17, 3389:18, 3398:8, 3403:15, 3403:16, 3403:25, 3404:1, 3406:5, 3406:11, 3406:22, 3406:25, 3407:10, 3420:12, 3420:13, 3421:18, 3422:13, 3422:14, 3423:4, 3423:5, 3423:12, 3424:17, 3424:20, 3424:21, 3426:7, 3433:22, 3433:23, 3434:20, 3434:21, 3435:6, 3435:14, 3436:18, 3436:21, 3437:2, 3437:6, 3437:7, 3437:9, 3437:10, 3439:14, 3439:24, 3440:5, 3440:24, 3440:25, 3441:5, 3442:1, 3442:21, 3443:1, 3443:21, 3447:17, 3447:18, 3448:20, 3449:19, 3449:20, 3449:21, 3452:22, 3452:23, 3454:8, 3454:9, 3461:20, 3462:5, 3463:7, 3463:20, 3465:24, 3466:23, 3467:9, 3467:15, 3467:20, 3468:4, 3469:7, 3471:17, 3472:24, 3473:13, 3474:3, 3475:23, 3475:24, 3478:23, 3479:5, 3479:6, 3480:21, 3481:19, 3481:23, 3483:11, 3483:16, 3483:17, 3483:19, 3484:15, 3484:16, 3485:20, 3490:3, 3493:8, 3494:1, 3494:23, 3494:24, 3495:1, 3495:3, 3495:4, 3495:7, 3495:11, 3495:12, 3495:14, 3495:15, 3495:17, 3495:18, 3495:22, 3495:23, 3495:25, 3496:3, 3496:4, 3496:7, 3496:8, 3496:10, 3496:11, 3496:13, 3496:14, 3496:16, 3496:17, 3496:19, 3496:20, 3496:22, 3496:23, 3496:25, 3497:1, 3497:4, 3497:9, 3497:13, 3497:14, 3497:16, 3497:17, 3497:24, 3497:25, 3498:10, 3498:15, 3498:16, 3499:9, 3499:10, 3499:14, 3499:15, 3499:19, 3500:6, 3500:11, 3500:12, 3500:15, 3500:16, 3502:2, 3502:6, 3502:9, 3502:12, 3502:21, 3503:1, 3503:15, 3504:1, 3504:2, 3504:10, 3504:11, 3504:12, 3504:23, 3505:12, 3505:13, 3505:17, 3506:1, 3507:1, 3508:21, 3508:22, 3508:24, 3508:25, 3509:2, 3510:4, 3510:5, 3510:14, 3511:22, 3511:23, 3512:3, 3512:4, 3512:8, 3512:9, 3512:10, 3512:12, 3512:15, 3513:15, 3513:18, 3513:23, 3514:13, 3514:22, 3515:8, 3515:9, 3515:16, 3515:22, 3516:2, 3516:5, 3516:7, 3516:11, 3516:12, 3516:22, 3516:24, 3517:13, 3517:24, 3517:25, 3518:3, 3518:4, 3520:2, 3520:12, 3521:7, 3521:11, 3521:19, 3521:22, 3521:25, 3522:3, 3522:8, 3522:11, 3523:21, 3525:7, 3525:10, 3525:18, 3525:25, 3526:9, 3526:11, 3526:18, 3526:21, 3526:22, 3526:25, 3527:16, 3527:17, 3527:19, 3530:19, 3531:1, 3531:11, 3531:20, 3532:16, 3533:22, 3534:6, 3535:4, 3535:5, 3535:7, 3535:18, 3535:23, 3535:24, 3536:1, 3536:2, 3536:4, 3536:7, 3536:8, 3536:11, 3537:10, 3539:15, 3539:16, 3539:18, 3540:14, 3540:19, 3540:22, 3540:23, 3541:4, 3541:7, 3541:9, 3542:8, 3542:15, 3542:18, 3542:25, 3543:3, 3544:18, 3544:25, 3545:6, 3545:10, 3545:19, 3545:20, 3546:24, 3547:3, 3548:2, 3548:19, 3550:1, 3550:9, 3550:14, 3550:24, 3551:21, 3552:8, 3552:10, 3552:11, 3552:12, 3552:15, 3552:16, 3556:19, 3557:19, 3557:23, 3558:7, 3558:11, 3558:17, 3558:22, 3559:2, 3559:8, 3560:17, 3560:24, 3561:11, 3561:12, 3561:15, 3561:17, 3563:24, 3565:3, 3565:16, 3565:19, 3565:23, 3567:8, 3567:13, 3567:19, 3567:23, 3568:11, 3568:14, 3569:12, 3569:14, 3569:18, 3570:8, 3571:10, 3571:14, 3571:23, 3572:2, 3572:22, 3573:8, 3573:14, 3573:17, 3573:19, 3573:20, 3573:23, 3574:2, 3574:6, 3574:9, 3575:5, 3575:8, 3575:12, 3575:16, 3575:20, 3575:21, 3576:2, 3576:5, 3576:10, 3576:16, 3577:4, 3577:24, 3578:9, 3578:15, 3578:17, 3578:21, 3579:9, 3579:21, 3580:1, 3580:2, 3580:10, 3580:15, 3580:22, 3581:1, 3582:5, 3582:9, 3582:13, 3582:23, 3583:3, 3583:4, 3583:7, 3583:8, 3583:22, 3584:3, 3584:19, 3584:23, 3585:14, 3586:14, 3586:15, 3586:19, 3588:7, 3589:2, 3589:9, 3590:9, 3590:12, 3590:18, 3590:19, 3590:23, 3591:15, 3591:24,
---	---

3592:3, 3592:14,
3592:17, 3592:25,
3593:2, 3593:6,
3593:12, 3593:21,
3594:13, 3594:18,
3595:7, 3595:19,
3595:23, 3596:1,
3596:4, 3596:10,
3596:20, 3597:4,
3597:5, 3598:14,
3598:20, 3598:24,
3599:4, 3599:8,
3599:24, 3601:20,
3601:21, 3601:23,
3602:3, 3602:5,
3604:21, 3604:25,
3605:21, 3606:1,
3606:4, 3606:7,
3606:14, 3606:18,
3606:24, 3607:4,
3608:10, 3608:13,
3608:18, 3608:21,
3608:24, 3609:6,
3609:8, 3610:7,
3611:2, 3611:16,
3611:22, 3612:24,
3613:9, 3613:13,
3613:19, 3615:11,
3615:15, 3616:2,
3616:13, 3617:22,
3617:25, 3619:2,
3620:1, 3620:6,
3620:24, 3621:3,
3621:8, 3621:11,
3623:7, 3625:14,
3630:5, 3630:14,
3631:19, 3632:2,
3632:11, 3633:17,
3633:18, 3634:2,
3634:11, 3634:15,
3636:7, 3636:11,
3636:17, 3637:3,
3637:19, 3639:3,
3639:5, 3639:12,
3639:19, 3641:12,
3641:13
correction [1] -
3509:20
correctly [26] -
3469:19, 3494:20,
3498:1, 3507:20,
3507:21, 3508:15,
3511:3, 3511:4,
3511:14, 3518:12,
3518:13, 3554:3,
3554:4, 3566:21,
3569:3, 3570:20,
3570:21, 3581:21,
3585:23, 3585:24,
3587:2, 3587:9,
3587:22, 3594:6,

3594:7, 3595:18
Cosson [11] -
3434:24, 3434:25,
3435:19, 3542:5,
3542:7, 3543:7,
3543:19, 3623:21,
3623:24, 3625:3
Cosson's [1] -
3636:9
costs [1] - 3401:22
counsel [17] -
3386:15, 3407:19,
3412:22, 3472:9,
3472:11, 3476:13,
3609:15, 3618:12,
3620:16, 3622:19,
3623:12, 3623:20,
3628:6, 3630:12,
3631:18, 3635:17,
3641:3
Counsel [1] -
3452:12
count [2] - 3473:17,
3594:21
counted [1] -
3557:18
counter [1] - 3414:20
countless [2] -
3442:11, 3507:14
countries [2] -
3380:5, 3524:22
COUNTY [1] - 3375:9
COUNTY/CIVIL [1] -
3375:1
couple [10] -
3427:21, 3460:25,
3484:10, 3503:12,
3507:11, 3509:16,
3520:8, 3529:9,
3549:14, 3594:23
coupled [1] -
3566:17
course [13] - 3406:2,
3410:12, 3412:13,
3425:6, 3426:19,
3438:20, 3441:23,
3547:16, 3582:15,
3619:12, 3621:22,
3624:14, 3625:5
court [3] - 3402:25,
3403:5, 3430:20
COURT [88] - 3375:1,
3379:1, 3379:6,
3379:17, 3386:15,
3386:19, 3394:18,
3405:9, 3407:18,
3407:22, 3408:8,
3408:12, 3408:23,
3409:3, 3409:9,
3409:12, 3409:22,

3410:17, 3411:7,
3414:14, 3414:17,
3415:25, 3416:24,
3417:18, 3418:6,
3418:17, 3418:22,
3419:9, 3419:22,
3420:1, 3420:5,
3422:16, 3422:24,
3431:24, 3438:9,
3450:1, 3450:18,
3451:6, 3451:12,
3452:11, 3452:14,
3464:22, 3471:10,
3486:10, 3486:14,
3489:3, 3492:6,
3492:14, 3492:19,
3507:24, 3518:21,
3518:25, 3519:4,
3519:9, 3527:22,
3529:20, 3537:23,
3538:4, 3538:22,
3554:8, 3554:10,
3554:18, 3554:22,
3600:8, 3601:9,
3603:9, 3607:19,
3609:9, 3618:16,
3620:12, 3625:8,
3626:15, 3627:2,
3628:3, 3628:24,
3629:17, 3631:12,
3632:25, 3633:7,
3635:11, 3635:17,
3638:3, 3638:6,
3640:3, 3641:15,
3641:17, 3641:23,
3642:4
Court [5] - 3405:9,
3427:23, 3431:17,
3643:6, 3643:16
court-appointed [1]
- 3402:25
COURTHOUSE [1] -
3375:9
courtroom [9] -
3379:4, 3408:21,
3420:3, 3492:9,
3492:17, 3518:22,
3554:13, 3554:20,
3642:1
cover [2] - 3555:11,
3626:20
covered [9] - 3461:4,
3461:7, 3461:24,
3555:12, 3555:15,
3570:13, 3582:11,
3631:3, 3638:17
covering [1] -
3406:13
covers [3] - 3452:25,
3569:18, 3634:7

CR [1] - 3505:7
CRAWFORD [1] -
3377:3
create [2] - 3394:10,
3400:20
created [2] - 3467:8,
3574:17
credentials [1] -
3394:17
credit [1] - 3404:16
criterion [1] -
3596:24
critical [13] - 3424:6,
3448:8, 3448:9,
3459:18, 3464:18,
3465:1, 3470:6,
3472:24, 3474:19,
3543:17, 3603:1,
3622:5, 3623:22
CROSS [1] - 3492:22
cross [9] - 3405:8,
3412:15, 3414:21,
3416:4, 3418:17,
3446:2, 3446:4,
3629:14
Cross [1] - 3378:4
CROSS-
EXAMINATION [1] -
3492:22
cross-examined [1]
- 3412:15
cross-section [2] -
3446:2, 3446:4
crossing [7] -
3429:2, 3455:7,
3456:3, 3456:8,
3462:3, 3617:11
crossover [1] -
3528:15
CRR [3] - 3375:23,
3643:4, 3643:15
cumulative [5] -
3416:18, 3416:25,
3419:8, 3419:20,
3486:5
cure [5] - 3500:10,
3537:5, 3537:8,
3537:9, 3538:7
cures [1] - 3537:25
curl [1] - 3615:21
curled [4] - 3386:9,
3487:11, 3487:20,
3488:24
curling [5] - 3485:5,
3485:7, 3485:12,
3486:3, 3487:8
current [1] - 3643:8
curtail [1] - 3530:7
cut [7] - 3446:9,
3528:4, 3554:2,

3616:16, 3634:5,
3634:19
cutoff [10] - 3458:10,
3458:19, 3459:18,
3603:1, 3605:12,
3610:6, 3612:9,
3612:15, 3623:3,
3623:4
cutting [1] - 3526:8
CV [3] - 3380:12,
3388:18, 3399:1
Cv [1] - 3375:16
cystocele [4] -
3509:14, 3509:20,
3518:6, 3518:8
cystoceles [2] -
3509:13, 3510:14
daily [1] - 3493:15
damage [4] - 3388:5,
3433:9, 3546:12,
3551:7
damaged [1] -
3551:12
damages [1] -
3514:1
Dan [5] - 3465:8,
3465:9, 3473:7,
3473:24, 3620:3
Dan's [1] - 3465:22
dangerous [3] -
3485:16, 3491:17,
3491:22
Daniel [1] - 3582:23
DANZIG [1] - 3377:3
data [20] - 3425:11,
3460:9, 3460:20,
3464:17, 3464:25,
3482:22, 3524:3,
3543:23, 3598:5,
3612:8, 3617:8,
3617:12, 3621:6,
3624:14, 3624:16,
3624:19, 3624:22,
3625:1, 3625:23,
3625:25
DATE [1] - 3375:11
date [6] - 3413:20,
3510:3, 3511:21,
3542:24, 3545:8,
3635:8
dated [1] - 3569:14
dates [2] - 3512:22,
3513:6
dating [1] - 3450:8
David [2] - 3415:12,
3635:3
DAVID [1] - 3376:3
Dawley [2] - 3568:3,
3568:9
day-to-day [2] -

3410:13, 3412:13
days [10] - 3399:23,
 3406:13, 3528:9,
 3529:9, 3530:5,
 3565:12, 3565:14,
 3568:4, 3568:17,
 3579:17
deal [8] - 3418:18,
 3419:8, 3486:10,
 3519:8, 3548:17,
 3563:3, 3589:24
dealing [2] -
 3388:23, 3529:17
decade [1] - 3393:17
decades [1] - 3578:6
December [3] -
 3498:8, 3609:10,
 3623:1
decide [1] - 3590:24
decided [2] -
 3474:17, 3475:15
decision [1] - 3534:7
decisions [1] -
 3412:3
decisive [1] -
 3564:21
deemed [1] -
 3402:11
deep [3] - 3584:12,
 3626:23, 3632:24
deeper [1] - 3388:1
defective [3] -
 3491:12, 3491:15,
 3518:11
defects [2] -
 3553:24, 3595:5
Defendant's [15] -
 3508:5, 3511:16,
 3534:24, 3540:25,
 3541:1, 3544:14,
 3545:13, 3549:13,
 3571:6, 3572:4,
 3578:13, 3581:23,
 3585:5, 3589:5,
 3595:20
Defendants [2] -
 3375:6, 3377:6
defendants [1] -
 3519:4
defense [18] -
 3413:11, 3413:18,
 3418:3, 3444:9,
 3472:9, 3472:11,
 3476:13, 3530:1,
 3530:7, 3609:15,
 3618:12, 3620:16,
 3622:19, 3623:12,
 3623:20, 3628:6,
 3630:12, 3631:18
Defense [1] - 3552:6

define [14] - 3392:22,
 3392:25, 3393:21,
 3396:15, 3420:22,
 3421:6, 3433:7,
 3442:5, 3458:11,
 3466:7, 3474:18,
 3490:23, 3616:19
defined [9] -
 3433:14, 3433:16,
 3433:18, 3433:21,
 3433:25, 3466:4,
 3481:10, 3481:14,
 3574:22
defines [1] - 3424:7
defining [1] -
 3427:10
definitely [9] -
 3384:15, 3417:8,
 3483:4, 3504:2,
 3527:12, 3547:20,
 3627:16, 3628:19,
 3630:6
definition [8] -
 3449:9, 3481:24,
 3545:22, 3546:1,
 3546:3, 3574:11,
 3574:21, 3604:11
deformation [7] -
 3461:13, 3461:16,
 3478:20, 3485:6,
 3485:8, 3489:19,
 3616:2
degradation [1] -
 3578:8
degree [3] - 3422:8,
 3427:24, 3428:3
degrees [2] -
 3622:15, 3624:8
delay [1] - 3543:13
deliberate [1] -
 3408:13
deliver [1] - 3383:14
demonstrate [2] -
 3486:22, 3636:16
demonstrates [1] -
 3485:1
dense [1] - 3619:15
department [17] -
 3381:9, 3383:12,
 3383:16, 3388:20,
 3389:17, 3389:20,
 3390:3, 3391:5,
 3391:19, 3392:9,
 3393:13, 3395:10,
 3430:9, 3448:21,
 3480:11, 3552:14,
 3582:14
Department [5] -
 3564:6, 3564:10,
 3583:1, 3583:2,

3593:5
dependent [1] -
 3443:23
deposition [15] -
 3399:23, 3407:6,
 3410:24, 3428:8,
 3462:11, 3494:4,
 3494:8, 3522:23,
 3522:24, 3522:25,
 3523:11, 3530:21,
 3577:17, 3602:7,
 3620:6
depositions [3] -
 3406:12, 3434:3,
 3491:9
Deprest [10] -
 3592:25, 3593:1,
 3593:2, 3594:13,
 3594:15, 3594:17,
 3603:15, 3607:13,
 3622:14, 3623:1
deps@golkow.com
 [1] - 3375:24
derives [1] - 3457:10
describe [2] -
 3546:3, 3579:2
described [5] -
 3392:6, 3471:19,
 3486:9, 3505:23,
 3506:20
design [26] -
 3394:12, 3413:23,
 3415:22, 3416:1,
 3420:23, 3426:6,
 3426:11, 3427:1,
 3427:7, 3428:15,
 3431:16, 3433:7,
 3437:13, 3439:24,
 3442:5, 3442:8,
 3443:23, 3443:25,
 3449:12, 3461:25,
 3462:3, 3490:10,
 3490:21, 3548:5,
 3617:1, 3618:12
designated [7] -
 3410:23, 3411:4,
 3413:25, 3415:20,
 3430:24, 3431:8,
 3431:9
designation [2] -
 3413:6, 3413:24
designed [8] -
 3434:7, 3443:5,
 3443:9, 3490:6,
 3490:7, 3490:9,
 3569:22, 3638:22
designee [3] -
 3410:2, 3415:16,
 3418:14
designing [1] -

3427:10
desperate [1] -
 3630:22
despite [1] - 3450:12
destroy [1] - 3444:10
detail [1] - 3549:8
detailed [1] - 3627:4
details [4] - 3388:2,
 3425:8, 3510:18,
 3541:23
determination [1] -
 3588:1
determine [4] -
 3401:7, 3459:5,
 3465:1, 3641:12
determined [2] -
 3512:7, 3516:20
determines [1] -
 3424:9
develop [4] - 3489:9,
 3609:6, 3614:18,
 3614:20
developed [6] -
 3433:6, 3465:24,
 3514:16, 3514:24,
 3515:1, 3515:12
development [8] -
 3421:19, 3429:25,
 3450:11, 3465:18,
 3469:13, 3512:16,
 3513:4, 3621:24
Development [2] -
 3499:7, 3499:17
device [7] - 3392:12,
 3392:17, 3394:11,
 3404:10, 3429:5,
 3610:5, 3626:5
devices [2] -
 3385:21, 3386:3
devoted [1] - 3418:2
diagnosis [1] -
 3495:3
diagram [4] -
 3445:23, 3445:25,
 3462:17, 3487:18
diagrams [1] -
 3456:11
diameter [7] -
 3424:12, 3426:18,
 3464:3, 3464:7,
 3464:11, 3553:1,
 3605:9
differed [1] - 3576:4
difference [4] -
 3442:14, 3455:3,
 3577:22, 3630:10
differences [2] -
 3528:24, 3528:25
different [50] -
 3389:7, 3391:11,

3392:7, 3393:4,
 3393:12, 3393:23,
 3395:23, 3400:25,
 3401:4, 3401:5,
 3423:12, 3454:16,
 3462:21, 3466:8,
 3466:19, 3466:22,
 3467:3, 3468:24,
 3474:13, 3474:15,
 3476:20, 3489:10,
 3500:14, 3501:1,
 3501:4, 3506:22,
 3520:3, 3520:4,
 3525:9, 3529:22,
 3536:9, 3544:11,
 3553:7, 3558:21,
 3563:23, 3570:19,
 3575:19, 3576:1,
 3585:17, 3590:25,
 3597:24, 3598:7,
 3610:10, 3610:12,
 3616:17, 3616:21,
 3629:4, 3630:4,
 3632:10
differentiate [4] -
 3395:25, 3596:24,
 3606:19, 3612:12
differentiation [1] -
 3423:7
difficult [4] -
 3391:17, 3508:11,
 3630:20, 3633:2
dimensional [5] -
 3461:10, 3586:25,
 3630:16, 3630:17,
 3631:22
Din [1] - 3519:21
DIRE [1] - 3379:19
dire [1] - 3394:14
Dire [1] - 3378:6
DIRECT [2] -
 3379:19, 3405:14
Direct [1] - 3378:4
direct [5] - 3498:18,
 3529:22, 3529:23,
 3533:9, 3537:20
direction [1] -
 3431:10
directions [6] -
 3468:10, 3469:22,
 3472:4, 3473:10,
 3475:23, 3553:23
directly [3] -
 3397:23, 3420:11,
 3446:3
director [2] -
 3389:25, 3635:3
directors [1] -
 3390:2
disadvantage [2] -

<p>3428:25, 3471:25 disagree [1] - 3631:11 disappear [1] - 3476:10 disappeared [2] - 3476:7, 3478:13 disastrous [1] - 3429:9 discomfort [2] - 3484:21, 3507:7 discovered [1] - 3394:19 discovery [1] - 3415:19 discuss [3] - 3409:16, 3430:10, 3633:1 discussed [6] - 3424:22, 3451:2, 3451:7, 3549:4, 3549:5, 3586:11 discussing [9] - 3394:2, 3450:8, 3452:21, 3464:16, 3472:2, 3472:23, 3487:8, 3534:15, 3593:10 discussion [7] - 3430:1, 3457:8, 3459:14, 3522:17, 3534:11, 3534:14, 3537:12 discussions [4] - 3423:6, 3429:22, 3527:4, 3638:14 disease [1] - 3388:6 diseases [2] - 3388:4, 3445:14 disputed [1] - 3460:7 disregard [3] - 3620:13, 3625:9, 3628:4 distance [12] - 3446:14, 3446:19, 3447:6, 3447:12, 3448:7, 3455:3, 3463:15, 3463:25, 3573:6, 3573:17, 3574:1, 3588:5 distinct [1] - 3469:17 distributed [1] - 3468:14 DIVISION [1] - 3375:1 Division [1] - 3583:1 DLTB00026 [1] - 3589:5 DLTB00045 [1] - 3534:24</p>	<p>DLTB00104 [1] - 3575:3 DLTB00139 [2] - 3552:6, 3592:19 DLTB00140 [1] - 3594:12 DLTB00150 [1] - 3581:24 DLTB00170 [1] - 3508:5 DLTB00259 [1] - 3578:13 DLTB00261 [1] - 3595:20 DLTB00266 [2] - 3544:14, 3571:6 DLTB00325 [1] - 3511:16 DLTB00647 [1] - 3499:11 DLTB00863 [1] - 3563:20 DLTB00864 [1] - 3567:17 DLTB00865 [1] - 3569:6 DLTB360 [1] - 3586:2 dmazie@mskf.net [1] - 3376:6 DOCKET [1] - 3375:2 Doctor [7] - 3427:20, 3441:11, 3484:25, 3508:4, 3530:15, 3567:18, 3632:25 doctor [6] - 3383:17, 3472:13, 3593:16, 3593:17, 3593:18, 3603:11 doctors [9] - 3500:13, 3510:12, 3517:12, 3535:23, 3542:10, 3564:12, 3584:17, 3593:21, 3595:1 document [16] - 3438:21, 3438:22, 3479:22, 3479:24, 3481:6, 3482:9, 3490:3, 3541:16, 3541:20, 3544:17, 3545:6, 3548:24, 3571:8, 3571:9, 3572:13, 3612:3 documented [1] - 3465:17 documents [24] - 3406:5, 3406:18, 3407:2, 3408:15, 3428:8, 3434:4,</p>	<p>3457:9, 3460:15, 3462:11, 3468:23, 3478:2, 3479:13, 3480:4, 3480:24, 3488:16, 3491:10, 3541:7, 3542:8, 3572:11, 3615:9, 3615:10, 3616:25, 3633:3, 3641:11 DOES [1] - 3375:6 dog [2] - 3637:23, 3637:24 dogs [1] - 3540:11 dollars [1] - 3493:25 domestic [1] - 3564:25 done [54] - 3381:16, 3383:11, 3389:9, 3392:12, 3393:16, 3394:2, 3394:3, 3394:22, 3403:11, 3404:20, 3404:23, 3406:21, 3408:9, 3412:11, 3412:12, 3412:14, 3413:3, 3433:17, 3433:23, 3439:5, 3444:11, 3449:12, 3449:15, 3453:19, 3453:22, 3461:15, 3463:24, 3467:5, 3470:12, 3473:1, 3473:13, 3473:14, 3473:23, 3474:2, 3477:1, 3477:4, 3477:8, 3477:21, 3478:20, 3482:3, 3482:14, 3483:2, 3486:6, 3497:19, 3534:10, 3538:1, 3549:10, 3562:2, 3577:20, 3584:22, 3597:14, 3599:3, 3612:17, 3617:5 door [2] - 3414:7, 3601:2 dots [1] - 3606:24 double [3] - 3403:12, 3484:2, 3484:3 doubt [2] - 3429:14, 3514:14 doubts [1] - 3488:7 down [52] - 3421:12, 3433:22, 3439:16, 3461:12, 3499:13, 3504:4, 3505:19, 3506:13, 3506:14, 3507:11, 3507:22, 3517:7, 3518:15, 3528:22, 3528:23,</p>	<p>3529:10, 3529:11, 3536:4, 3540:2, 3540:16, 3540:24, 3543:24, 3547:5, 3550:20, 3552:19, 3563:19, 3564:8, 3564:24, 3566:23, 3567:15, 3567:25, 3570:10, 3570:23, 3571:3, 3571:13, 3572:24, 3575:1, 3578:1, 3578:4, 3578:11, 3578:24, 3579:23, 3582:7, 3583:15, 3583:24, 3587:4, 3590:20, 3595:4, 3596:8, 3631:24, 3636:22, 3637:7 downsides [1] - 3419:4 dozen [3] - 3403:3, 3403:4 dozens [3] - 3399:16, 3399:17, 3407:5 DR [2] - 3378:5, 3379:11 Dr [77] - 3379:9, 3379:22, 3380:10, 3381:25, 3395:17, 3405:4, 3412:5, 3416:7, 3416:14, 3416:19, 3420:9, 3423:15, 3424:17, 3425:15, 3428:10, 3429:11, 3429:15, 3434:19, 3435:19, 3437:16, 3438:22, 3440:2, 3440:16, 3446:6, 3449:7, 3450:25, 3453:14, 3454:5, 3454:11, 3460:24, 3461:23, 3472:5, 3472:9, 3472:11, 3472:13, 3474:9, 3476:4, 3476:13, 3480:25, 3484:12, 3484:17, 3485:19, 3486:4, 3487:2, 3489:12, 3489:14, 3490:13, 3492:25, 3542:7, 3543:7, 3543:19, 3545:2, 3555:1, 3555:5, 3555:6, 3555:13, 3556:3, 3556:8, 3559:20, 3566:25, 3574:14, 3585:25, 3586:1,</p>	<p>3586:11, 3595:25, 3596:10, 3597:11, 3601:19, 3603:10, 3608:12, 3608:17, 3623:24, 3625:12, 3635:10, 3636:9 drafted [1] - 3411:22 drawing [1] - 3484:4 drew [1] - 3619:18 dropped [3] - 3416:19, 3416:21 due [4] - 3397:1, 3435:9, 3488:18, 3527:12 duly [1] - 3379:11 duplicate [1] - 3419:10 during [11] - 3382:16, 3383:11, 3385:13, 3386:3, 3387:11, 3388:12, 3393:17, 3422:1, 3469:13, 3475:10, 3551:11 dwelt [1] - 3586:10 DynaMesh [21] - 3556:12, 3558:6, 3558:9, 3558:16, 3558:25, 3559:6, 3559:7, 3559:10, 3562:16, 3563:5, 3589:8, 3610:10, 3610:13, 3615:14, 3616:4, 3616:8, 3616:12, 3616:22, 3616:24, 3617:13 dynamic [1] - 3429:10 dyspareunia [1] - 3437:20 dyspareunia... indeed [1] - 3435:23 e-mail [20] - 3431:23, 3434:23, 3435:7, 3435:12, 3435:16, 3436:20, 3437:18, 3465:7, 3469:10, 3473:24, 3480:7, 3480:17, 3484:9, 3484:11, 3541:3, 3603:7, 3603:11, 3623:20, 3636:9 e-mailing [1] - 3542:20 e-mails [7] - 3434:19, 3436:5, 3436:17, 3439:15, 3449:10, 3543:10, 3625:11 early [5] - 3396:2,</p>
---	--	---	--	--

3451:4, 3460:3,
3503:14, 3503:19
ease [4] - 3527:16,
3527:18
easier [4] - 3512:25,
3630:19, 3632:18,
3632:22
easily [1] - 3529:7
East [1] - 3376:15
eastern [1] - 3380:2
easy [2] - 3391:19,
3629:5
eat [1] - 3606:1
Eberhard [3] -
3484:13, 3484:17,
3625:12
edges [1] - 3633:16
edition [1] - 3589:19
editor [3] - 3600:7,
3600:9, 3600:17
educate [1] -
3415:18
education [1] -
3380:23
effect [3] - 3418:10,
3588:3, 3621:7
effective [28] -
3472:3, 3472:6,
3472:7, 3477:10,
3478:22, 3482:8,
3516:9, 3516:11,
3555:2, 3556:19,
3557:23, 3558:1,
3558:3, 3558:13,
3559:1, 3559:8,
3563:16, 3567:7,
3586:4, 3587:20,
3588:21, 3596:17,
3596:22, 3597:3,
3599:6, 3638:24,
3639:7, 3639:15
effectively [1] -
3518:8
effects [1] - 3392:24
efficacy [3] - 3512:7,
3516:20, 3535:10
eight [5] - 3450:6,
3484:14, 3584:5,
3585:9, 3593:21
Eisenhower [1] -
3376:4
either [9] - 3395:20,
3397:24, 3410:25,
3415:13, 3489:20,
3525:6, 3536:10,
3565:1, 3607:13
elastic [1] - 3461:14
elasticity [1] - 3554:1
elective [1] - 3585:9
elements [2] -

3594:4, 3595:16
eliminate [1] -
3444:10
Elmer [1] - 3582:22
elongation [5] -
3461:15, 3475:2,
3475:5, 3475:8,
3478:20
emphasis [1] -
3417:16
employed [3] -
3465:18, 3494:4,
3560:2
employee [2] -
3430:6, 3430:8
employees [1] -
3391:12
employment [1] -
3507:8
encapsulate [1] -
3479:4
end [15] - 3385:1,
3385:2, 3408:16,
3440:18, 3446:7,
3449:3, 3456:11,
3520:15, 3566:12,
3581:4, 3581:12,
3594:9, 3624:3
ended [9] - 3423:19,
3432:12, 3451:15,
3486:18, 3530:12,
3539:8, 3597:12,
3601:12, 3627:8
endings [1] -
3632:10
endoscopic [1] -
3564:22
endpoints [2] -
3570:2, 3570:3
ends [1] - 3423:22
engineer [2] -
3471:11, 3480:18
engineering [9] -
3381:4, 3381:6,
3391:4, 3391:6,
3391:9, 3391:13,
3392:10, 3405:6,
3618:5
Engineering [1] -
3560:5
engineers [1] -
3391:12
English [1] - 3543:11
enlarge [1] - 3421:13
enormous [3] -
3405:22, 3507:13,
3529:1
entered [1] - 3517:3
enters [4] - 3379:4,
3420:3, 3492:17,

3554:20
entire [12] - 3382:4,
3389:25, 3391:7,
3394:1, 3429:5,
3429:7, 3456:15,
3476:11, 3493:22,
3508:18, 3579:3,
3626:25
entitled [2] -
3410:14, 3412:17
environment [1] -
3635:5
EP [2] - 3563:16,
3563:17
equal [3] - 3493:11,
3519:1, 3573:14
erosion [5] - 3435:7,
3435:25, 3437:15,
3533:3, 3634:20
esophageal [1] -
3528:17
esophagus [4] -
3390:16, 3634:14,
3634:19, 3634:20
especially [1] -
3445:17
ESQUIRE [7] -
3376:3, 3376:4,
3376:9, 3376:14,
3376:19, 3376:19,
3377:3
essential [5] -
3388:10, 3434:10,
3434:11, 3442:5,
3442:7
essentially [2] -
3526:2, 3536:24
establish [4] -
3395:21, 3538:24,
3555:20, 3600:22
established [3] -
3392:20, 3396:1,
3530:17
estimate [5] -
3463:6, 3475:8,
3481:12, 3524:1,
3537:1
estimated [1] -
3478:3
et [4] - 3450:8,
3592:9, 3592:17,
3594:15
ETHICON [1] -
3375:5
Ethicon [102] -
3376:23, 3393:5,
3393:10, 3393:13,
3393:18, 3394:5,
3399:12, 3399:19,
3399:22, 3399:24,

3400:1, 3400:17,
3406:4, 3411:11,
3424:15, 3424:18,
3424:24, 3428:10,
3429:12, 3429:18,
3430:6, 3430:25,
3431:6, 3431:7,
3431:11, 3432:7,
3432:17, 3432:18,
3433:17, 3435:4,
3437:8, 3438:25,
3439:2, 3440:5,
3447:16, 3449:4,
3460:4, 3460:5,
3460:13, 3462:13,
3463:17, 3463:22,
3465:6, 3465:10,
3466:13, 3467:13,
3467:23, 3468:8,
3468:17, 3473:7,
3475:9, 3477:3,
3477:9, 3477:11,
3477:20, 3478:2,
3479:13, 3480:12,
3480:18, 3480:24,
3482:8, 3482:25,
3483:2, 3485:20,
3488:17, 3488:22,
3489:22, 3491:10,
3491:24, 3493:3,
3514:24, 3514:25,
3515:4, 3515:7,
3515:12, 3531:8,
3531:25, 3541:3,
3542:21, 3559:6,
3559:16, 3560:3,
3560:13, 3560:17,
3562:10, 3562:12,
3562:13, 3562:14,
3572:13, 3579:25,
3598:13, 3598:22,
3599:21, 3611:8,
3612:2, 3616:25,
3620:4, 3624:21,
3625:11, 3629:11,
3635:3, 3641:11
Ethicon's [7] -
3429:23, 3453:23,
3483:10, 3512:21,
3513:4, 3513:5,
3615:9
ETHUS [1] - 3542:20
Europe [4] -
3381:11, 3427:18,
3597:14, 3598:19
European [5] -
3511:20, 3511:24,
3516:16, 3597:16,
3598:23
Euros [7] - 3493:12,

3494:1, 3494:9,
3494:10, 3494:12,
3494:14
evaluated [2] -
3583:10, 3601:18
evaluating [1] -
3410:7
evaluation [5] -
3535:10, 3578:20,
3585:21, 3601:24,
3626:7
events [1] - 3411:16
eventually [1] -
3464:13
everyday [3] -
3570:16, 3638:20,
3639:9
evidence [11] -
3408:14, 3411:9,
3451:10, 3452:8,
3543:22, 3612:15,
3624:9, 3624:11,
3624:15
exact [1] - 3517:6
exactly [19] - 3385:4,
3387:15, 3465:24,
3470:8, 3482:11,
3486:4, 3503:25,
3504:14, 3535:1,
3536:18, 3548:14,
3549:7, 3577:19,
3584:12, 3608:1,
3608:14, 3611:20,
3614:12, 3624:18
exam [1] - 3533:9
EXAMINATION [6] -
3379:19, 3405:14,
3492:22, 3597:8,
3636:2, 3640:15
examination [5] -
3498:18, 3517:9,
3517:13, 3517:20,
3587:5
examinations [4] -
3467:5, 3517:23,
3566:14, 3585:19
examine [4] -
3381:17, 3389:21,
3390:19, 3565:22
examined [8] -
3379:12, 3412:15,
3494:25, 3495:5,
3495:7, 3495:13,
3495:16, 3568:19
example [6] -
3381:5, 3441:13,
3495:10, 3496:6,
3536:16, 3562:16
exceed [1] - 3588:5
exceeding [2] -

3550:13, 3623:11
excellent [3] -
 3558:25, 3559:1,
 3563:1
except [3] - 3402:17,
 3417:19, 3536:6
exceptions [1] -
 3600:18
excessive [2] -
 3456:25, 3471:24
exchange [1] -
 3493:24
exchanged [2] -
 3393:24, 3482:5
exclusive [1] -
 3581:19
excused [1] - 3642:6
Exhibit [13] - 3508:5,
 3511:16, 3534:24,
 3540:3, 3540:25,
 3541:2, 3544:14,
 3571:6, 3572:5,
 3578:13, 3581:23,
 3589:5, 3595:20
exhibit [2] - 3571:20,
 3600:12
existed [1] - 3413:13
existing [2] - 3490:8,
 3613:5
exists [1] - 3419:5
expansion [2] -
 3506:5, 3506:21
expect [5] - 3413:20,
 3419:10, 3487:14,
 3487:18, 3487:20
expected [2] -
 3475:4, 3475:10
experience [13] -
 3383:21, 3385:18,
 3397:6, 3404:3,
 3404:12, 3422:1,
 3439:7, 3488:5,
 3509:22, 3510:6,
 3529:14, 3610:21,
 3633:1
experiences [2] -
 3397:11, 3501:2
experimental [3] -
 3503:19, 3540:11,
 3566:14
experiments [4] -
 3490:20, 3568:10,
 3622:3, 3639:13
expert [52] - 3386:16,
 3402:25, 3403:6,
 3405:4, 3405:11,
 3405:18, 3405:23,
 3406:15, 3409:5,
 3409:18, 3410:6,
 3411:3, 3411:4,

3411:24, 3412:5,
 3414:12, 3415:4,
 3416:4, 3416:16,
 3417:25, 3419:10,
 3430:23, 3430:24,
 3431:6, 3431:8,
 3431:14, 3431:25,
 3432:3, 3432:6,
 3439:1, 3447:22,
 3449:3, 3449:18,
 3450:7, 3450:16,
 3453:10, 3495:19,
 3497:3, 3497:5,
 3512:18, 3512:20,
 3512:23, 3513:4,
 3514:16, 3521:12,
 3525:17, 3533:6,
 3537:21, 3543:23,
 3558:24, 3624:12,
 3629:11
expertise [6] -
 3392:17, 3404:4,
 3431:1, 3537:24,
 3539:3, 3633:1
experts [1] - 3486:5
explain [25] -
 3387:17, 3388:21,
 3390:1, 3390:8,
 3391:3, 3392:15,
 3394:22, 3412:18,
 3420:21, 3421:22,
 3424:2, 3433:24,
 3445:22, 3445:24,
 3445:25, 3474:12,
 3474:14, 3476:16,
 3487:7, 3487:22,
 3597:15, 3612:6,
 3612:7, 3624:6,
 3640:18
explained [3] -
 3471:1, 3471:21,
 3471:24
explaining [1] -
 3612:21
explains [1] -
 3455:13
explanation [2] -
 3471:7, 3474:7
explant [3] -
 3597:13, 3601:16,
 3612:4
explanted [4] -
 3448:17, 3448:22,
 3495:13, 3595:23
explants [13] -
 3423:19, 3448:24,
 3495:6, 3599:2,
 3599:14, 3600:11,
 3601:16, 3601:17,
 3602:1, 3602:8,

3602:10, 3602:22,
 3602:25
exponential [1] -
 3506:22
exposure [2] -
 3537:5, 3538:7
express [1] -
 3498:25
expressed [1] -
 3449:16
expressing [1] -
 3549:11
expression [1] -
 3574:10
extended [4] -
 3390:14, 3455:15,
 3507:15, 3511:10
extensive [2] -
 3393:16, 3404:7
extensively [1] -
 3424:22
extent [8] - 3396:16,
 3410:14, 3412:21,
 3417:20, 3422:8,
 3534:1, 3548:3,
 3581:17
external [2] - 3384:7,
 3384:23
extra [3] - 3571:13,
 3571:15, 3633:16
eye [1] - 3628:17
fabric [3] - 3553:9,
 3553:10, 3553:24
fabrics [3] - 3553:20,
 3553:21, 3590:23
facilities [1] - 3382:4
facility [4] - 3382:2,
 3382:9, 3389:25,
 3400:18
fact [29] - 3389:10,
 3400:17, 3409:20,
 3410:22, 3410:25,
 3411:20, 3412:6,
 3412:7, 3412:9,
 3412:14, 3422:8,
 3426:4, 3431:1,
 3431:9, 3431:12,
 3431:24, 3432:2,
 3434:5, 3439:21,
 3450:12, 3451:19,
 3461:24, 3500:13,
 3529:23, 3533:19,
 3611:24, 3618:19,
 3638:10, 3639:11
factor [2] - 3595:13,
 3603:16
factors [2] - 3452:17,
 3602:3
facts [1] - 3412:7
factual [3] - 3413:4,

3431:5, 3432:1
factually [2] -
 3413:17, 3414:9
Faculty [1] - 3593:5
fail [2] - 3481:25,
 3516:10
failed [1] - 3482:4
failure [3] - 3505:25,
 3518:9, 3532:8
failures [1] - 3629:6
fair [13] - 3389:8,
 3389:14, 3407:13,
 3419:21, 3425:24,
 3428:5, 3428:6,
 3508:14, 3508:19,
 3524:1, 3539:19,
 3542:11, 3558:13
Falconer [1] -
 3582:22
familiar [9] - 3410:9,
 3499:3, 3501:11,
 3502:1, 3508:6,
 3542:7, 3567:12,
 3567:21, 3578:14
familiarized [1] -
 3508:9
family [1] - 3494:11
famous [1] - 3381:3
Fang [1] - 3594:15
far [15] - 3414:10,
 3447:5, 3447:13,
 3459:17, 3475:12,
 3478:13, 3509:3,
 3524:17, 3528:1,
 3528:22, 3536:13,
 3537:24, 3538:25,
 3607:1, 3636:6
fascial [1] - 3595:5
fashion [6] -
 3461:10, 3461:11,
 3483:9, 3483:10,
 3553:25, 3634:5
fashioned [1] -
 3414:23
fat [14] - 3446:16,
 3456:22, 3458:10,
 3478:25, 3485:13,
 3605:20, 3605:22,
 3606:6, 3606:7,
 3606:8, 3607:2,
 3607:9, 3608:4,
 3632:13
fatty [6] - 3448:11,
 3602:16, 3602:24,
 3605:16, 3630:19,
 3632:7
favor [1] - 3588:13
favored [2] -
 3521:18, 3521:20
fax [1] - 3375:24

FBR [2] - 3549:4,
 3551:17
FBR [2] - 3547:9,
 3549:3
FDA [1] - 3413:16
fear [1] - 3436:9
February [2] -
 3375:11, 3542:24
feedback [1] -
 3598:2
FEG [16] - 3559:11,
 3559:18, 3559:21,
 3560:11, 3560:19,
 3560:24, 3561:6,
 3561:8, 3561:9,
 3561:19, 3562:5,
 3562:11, 3562:14,
 3562:17, 3563:5
fellowships [1] -
 3497:11
felt [2] - 3448:17,
 3448:20
female [1] - 3632:8
few [10] - 3406:7,
 3414:4, 3415:24,
 3462:25, 3467:2,
 3506:3, 3522:21,
 3605:24, 3606:2,
 3635:17
fiber [11] - 3423:21,
 3448:19, 3456:15,
 3456:18, 3502:18,
 3505:5, 3505:17,
 3550:13, 3553:1,
 3553:4, 3623:11
fiber-filaments [1] -
 3553:4
fibers [12] - 3446:8,
 3447:5, 3456:12,
 3457:24, 3487:24,
 3505:12, 3551:7,
 3551:11, 3553:6,
 3592:8, 3602:9,
 3619:24
fibroblast [2] -
 3595:13, 3603:16
fibroblasts [6] -
 3592:5, 3594:4,
 3595:15, 3604:16,
 3604:18, 3606:2
fibroplasia [1] -
 3592:7
fibrosis [17] -
 3396:16, 3396:18,
 3396:20, 3397:2,
 3443:19, 3446:24,
 3447:3, 3449:13,
 3459:8, 3459:22,
 3461:5, 3461:18,
 3606:21, 3607:8,

3610:22, 3619:25,
3622:24
Fibrosis [2] -
3443:13, 3443:17
fibrotic [15] -
3424:25, 3446:13,
3448:6, 3452:20,
3470:17, 3471:2,
3471:22, 3476:11,
3533:14, 3544:1,
3549:15, 3549:17,
3549:21, 3551:17,
3619:7
Fibrotic [1] - 3549:24
field [10] - 3382:7,
3393:15, 3404:11,
3428:9, 3437:17,
3488:9, 3491:7,
3527:2, 3532:8,
3598:6
fields [8] - 3401:11,
3405:4, 3405:11,
3440:23, 3441:3,
3497:13, 3519:16,
3520:16
fifth [1] - 3556:6
figure [5] - 3430:21,
3458:14, 3464:1,
3466:25, 3470:2
Figure [1] - 3553:19
figures [1] - 3523:14
filament [6] -
3446:12, 3447:14,
3457:22, 3457:23,
3553:14, 3553:25
filaments [24] -
3429:2, 3446:15,
3446:18, 3446:25,
3447:12, 3447:13,
3454:15, 3454:16,
3454:21, 3454:24,
3455:4, 3455:8,
3456:3, 3456:8,
3462:3, 3462:7,
3513:22, 3552:24,
3553:4, 3553:17,
3566:9, 3576:4,
3588:7, 3616:20
filed [1] - 3409:9
fill [1] - 3586:3
filled [11] - 3424:13,
3446:16, 3446:22,
3446:23, 3447:1,
3455:2, 3456:21,
3458:7, 3458:10,
3485:13, 3607:9
filling [3] - 3447:10,
3544:5, 3544:6
final [1] - 3613:25
finally [2] - 3385:5,

3626:22
findings [6] - 3424:2,
3424:21, 3425:19,
3602:9, 3602:15
fine [5] - 3394:20,
3408:7, 3549:23,
3572:8, 3603:12
finger [1] - 3444:8
finish [3] - 3512:19,
3528:21, 3551:9
finished [1] - 3381:1
first [54] - 3380:14,
3380:15, 3383:10,
3383:18, 3392:21,
3394:5, 3394:8,
3394:9, 3394:12,
3412:12, 3421:1,
3426:15, 3440:10,
3450:18, 3457:12,
3475:19, 3477:1,
3483:9, 3500:5,
3500:10, 3503:12,
3506:3, 3509:16,
3511:1, 3511:5,
3511:8, 3541:17,
3546:6, 3549:14,
3555:19, 3560:2,
3564:15, 3566:13,
3574:19, 3574:20,
3581:18, 3586:21,
3587:11, 3589:19,
3593:1, 3594:22,
3601:3, 3601:4,
3601:5, 3608:2,
3610:21, 3611:25,
3612:2, 3622:21,
3627:3, 3628:6,
3631:17, 3634:24
fistula [1] - 3385:22
fit [1] - 3464:12
fits [1] - 3458:6
five [15] - 3384:19,
3384:22, 3391:11,
3393:13, 3401:3,
3438:19, 3486:13,
3529:14, 3538:18,
3559:25, 3560:1,
3578:6, 3582:25,
3593:20, 3614:24
fixation [1] - 3632:4
fixed [1] - 3517:5
fixing [2] - 3506:25,
3537:10
flat [17] - 3386:4,
3484:23, 3487:15,
3488:13, 3514:17,
3515:13, 3543:18,
3586:24, 3587:8,
3623:22, 3630:13,
3630:15, 3631:17,

3632:2, 3632:3,
3632:18
flexibility [3] -
3595:13, 3603:17,
3616:21
flexible [3] -
3448:13, 3479:1,
3605:17
flip [6] - 3500:2,
3501:25, 3513:1,
3545:12, 3566:11,
3585:16
floor [47] - 3397:25,
3400:5, 3400:10,
3400:19, 3403:11,
3403:14, 3404:23,
3429:8, 3429:10,
3429:24, 3431:13,
3431:22, 3432:19,
3433:5, 3433:15,
3433:22, 3443:5,
3443:10, 3476:20,
3490:16, 3495:24,
3496:16, 3497:3,
3497:5, 3497:15,
3521:25, 3522:7,
3522:11, 3522:14,
3535:23, 3542:11,
3558:19, 3592:20,
3593:8, 3593:11,
3594:2, 3613:11,
3614:3, 3615:1,
3629:20, 3630:11,
3631:1, 3631:6,
3632:24, 3633:4,
3636:14
Floor [1] - 3376:5
flow [1] - 3526:9
fluoride [1] - 3610:17
fluorine [1] - 3610:19
focus [12] - 3380:19,
3391:7, 3391:8,
3396:3, 3404:10,
3416:1, 3433:8,
3453:24, 3457:14,
3580:13, 3599:19,
3625:2
focused [3] -
3415:21, 3459:9,
3467:17
fold [1] - 3453:5
folding [1] - 3422:2
folks [1] - 3429:18
follow [7] - 3434:5,
3508:1, 3510:17,
3517:10, 3517:21,
3535:11, 3536:17
follow-up [6] -
3508:1, 3510:17,
3517:10, 3517:21,

3535:11, 3536:17
followed [1] - 3434:5
following [10] -
3396:5, 3426:21,
3430:17, 3450:4,
3453:11, 3486:1,
3527:24, 3537:18,
3600:5, 3626:17
follows [2] -
3379:12, 3556:14
football [4] -
3440:23, 3441:3,
3519:16, 3520:16
for.. [1] - 3521:20
forbidden [1] -
3532:5
force [14] - 3475:21,
3476:5, 3478:6,
3478:8, 3478:10,
3483:9, 3483:14,
3483:15, 3488:2,
3489:20, 3489:21,
3615:20, 3616:1
forces [7] - 3476:3,
3476:20, 3478:3,
3483:8, 3489:23,
3497:15
foregoing [1] -
3643:7
foreign [38] - 3395:6,
3423:14, 3423:17,
3426:9, 3444:2,
3444:5, 3444:7,
3444:10, 3444:12,
3444:17, 3444:22,
3444:24, 3445:2,
3445:7, 3445:10,
3445:11, 3445:15,
3445:21, 3454:20,
3454:24, 3533:8,
3547:8, 3547:10,
3547:14, 3547:17,
3547:20, 3547:23,
3547:25, 3548:3,
3548:8, 3548:17,
3549:3, 3549:5,
3568:25, 3581:16,
3583:19, 3610:21,
3622:21
forever [2] - 3528:19,
3529:3
forgetting [1] -
3448:3
form [9] - 3388:12,
3436:9, 3441:20,
3470:25, 3487:24,
3487:25, 3488:11,
3497:12, 3544:4
formal [1] - 3497:12
Format [1] - 3643:8

formation [17] -
3385:23, 3422:2,
3424:4, 3424:8,
3429:5, 3444:25,
3455:8, 3455:15,
3456:1, 3456:19,
3457:1, 3458:8,
3458:20, 3462:7,
3471:24, 3569:1,
3599:16
formed [1] - 3430:25
forms [2] - 3445:17,
3463:9
forth [1] - 3412:9
fortisan [1] - 3500:21
fortunately [1] -
3395:15
forward [2] -
3459:11, 3508:10
forwarded [1] -
3480:20
foundation [1] -
3471:9
four [18] - 3393:25,
3403:3, 3403:4,
3440:23, 3441:3,
3474:15, 3517:2,
3519:16, 3520:16,
3537:4, 3556:6,
3556:11, 3558:14,
3593:20, 3614:18,
3617:24, 3618:22,
3618:25
four-and-a-half [1] -
3537:4
France [1] - 3543:6
free [13] - 3425:9,
3425:10, 3425:13,
3455:10, 3461:19,
3477:17, 3512:2,
3512:7, 3516:16,
3516:21, 3518:7,
3571:7, 3627:21
FREEMAN [1] -
3376:3
Friday [2] - 3484:10,
3528:2
friend [1] - 3457:10
front [6] - 3380:8,
3441:7, 3459:23,
3469:24, 3499:22,
3569:16
fulfills [2] - 3442:4,
3534:18
full [5] - 3379:14,
3390:11, 3390:20,
3507:7, 3643:8
fully [3] - 3381:22,
3547:7, 3549:1
function [10] -

3381:21, 3429:9,
3431:2, 3442:2,
3442:3, 3546:6,
3546:9, 3546:10,
3548:4, 3548:5
functional [3] -
3537:14, 3539:1,
3579:13
Functional [1] -
3578:19
fund [2] - 3402:11,
3424:15
funky [1] - 3572:25
Furthermore [2] -
3587:5, 3596:8
furthermore [1] -
3458:11
future [1] - 3394:3
GAGE [69] - 3376:19,
3394:13, 3405:8,
3407:20, 3427:3,
3430:13, 3430:15,
3430:18, 3437:23,
3438:1, 3438:7,
3449:22, 3450:5,
3452:9, 3452:13,
3464:20, 3471:8,
3477:23, 3483:20,
3485:23, 3486:2,
3487:16, 3489:2,
3492:20, 3492:24,
3508:3, 3518:23,
3519:2, 3519:7,
3519:10, 3519:12,
3529:13, 3530:14,
3538:2, 3538:5,
3539:10, 3554:6,
3554:9, 3554:24,
3554:25, 3597:6,
3600:3, 3600:6,
3600:15, 3601:7,
3602:11, 3603:5,
3603:8, 3603:25,
3609:7, 3620:10,
3625:7, 3626:12,
3628:1, 3628:21,
3629:13, 3630:25,
3631:7, 3632:23,
3635:7, 3636:4,
3638:5, 3638:8,
3640:1, 3640:8,
3640:9, 3640:13,
3641:14, 3641:22
Gage [5] - 3407:22,
3452:8, 3493:2,
3554:23, 3641:20
Gene [1] - 3435:17
general [7] -
3381:19, 3382:13,
3382:20, 3390:9,

3428:22, 3504:25,
3628:13
generally [2] -
3529:24, 3605:8
generated [1] -
3453:11
genetic [1] - 3549:6
geometries [1] -
3469:16
geometry [2] -
3453:25, 3596:23
German [2] - 3402:4,
3559:15
Germany [13] -
3380:4, 3381:3,
3383:9, 3384:13,
3385:2, 3401:19,
3402:4, 3402:25,
3403:6, 3427:18,
3522:24, 3543:9,
3598:9
given [3] - 3399:3,
3484:12, 3494:18
glad [1] - 3517:17
GOLKOW [1] -
3375:23
grade [2] - 3512:8,
3516:22
grading [1] - 3624:11
graft [1] - 3614:9
grail [2] - 3614:3,
3614:25
gram [3] - 3475:15,
3475:16, 3476:6
grams [2] - 3580:15,
3580:19
GRAND [1] - 3376:14
grand@bernlieb.
com [1] - 3376:16
grant [3] - 3401:20,
3562:23, 3579:25
granted [2] -
3559:22, 3560:21
grants [6] - 3401:15,
3401:18, 3401:19,
3402:3, 3402:6,
3402:7
granuloma [3] -
3447:6, 3550:12,
3623:11
granulomas [1] -
3456:12
great [5] - 3397:12,
3529:8, 3538:12,
3538:14, 3601:1
greater [23] -
3424:20, 3425:3,
3459:12, 3460:8,
3468:13, 3469:1,
3473:9, 3475:22,

3481:18, 3481:21,
3489:21, 3580:22,
3580:25, 3588:11,
3588:12, 3591:19,
3594:3, 3595:14,
3602:10, 3608:7,
3611:1, 3619:4
grew [1] - 3504:21
Griswald [1] -
3505:22
groin [9] - 3485:8,
3487:2, 3487:19,
3488:25, 3499:12,
3551:19, 3624:24,
3625:6, 3631:23
GROSS [2] - 3375:3
Gross [1] - 3411:2
gross [4] - 3494:22,
3495:3, 3495:14,
3495:17
Gross's [1] - 3450:6
ground [1] - 3542:11
group [13] - 3393:9,
3393:11, 3394:1,
3425:25, 3429:16,
3430:10, 3440:9,
3460:4, 3568:5,
3599:17, 3601:25
Group [3] - 3575:16,
3576:7, 3576:13
grouping [6] -
3598:3, 3598:11,
3598:25, 3599:13,
3599:18, 3599:23
groups [2] - 3596:25,
3598:7
grow [4] - 3448:11,
3604:13, 3605:2,
3608:4
growing [2] -
3481:22, 3605:10
grown [1] - 3579:19
growth [1] - 3506:22
guarantee [1] -
3482:16
guess [7] - 3573:22,
3574:14, 3584:8,
3589:20, 3593:19,
3593:22
guessing [1] -
3529:13
guidance [1] -
3479:18
guy [5] - 3411:24,
3416:5, 3442:19,
3538:16
guys [5] - 3483:18,
3560:5, 3560:10,
3568:19, 3581:8
GYNECARE [1] -

3375:5
Gynecare [3] -
3454:7, 3572:21,
3574:22
gynecological [2] -
3522:2, 3585:10
gynecologist [2] -
3403:24, 3497:8
gynecologists [2] -
3400:11, 3583:5
Gynecology [2] -
3583:2, 3593:6
gynecology [1] -
3552:15
Gynemesh [71] -
3391:24, 3408:2,
3428:11, 3428:23,
3434:8, 3436:1,
3438:14, 3439:9,
3439:24, 3445:18,
3447:23, 3449:5,
3450:12, 3454:1,
3461:4, 3464:18,
3465:11, 3466:13,
3469:2, 3470:13,
3470:24, 3471:6,
3472:21, 3475:21,
3477:4, 3483:2,
3491:11, 3491:25,
3496:15, 3498:14,
3505:15, 3515:5,
3515:8, 3515:19,
3515:21, 3516:5,
3539:19, 3540:22,
3553:8, 3553:9,
3571:25, 3572:22,
3574:22, 3577:7,
3577:10, 3577:11,
3577:12, 3577:13,
3577:15, 3580:17,
3586:19, 3611:9,
3611:12, 3613:19,
3613:22, 3615:2,
3615:14, 3615:21,
3615:23, 3615:24,
3615:25, 3616:13,
3616:15, 3617:2,
3617:6, 3617:21,
3618:18, 3620:20,
3634:2, 3636:7,
3639:14
Gynemesh/Prolift
[1] - 3586:5
habilitacion [1] -
3387:1
half [13] - 3406:2,
3406:24, 3478:21,
3478:22, 3483:18,
3483:24, 3492:7,
3528:15, 3537:4,

3550:13, 3600:24,
3613:18, 3623:12
halfway [1] - 3596:8
Hamburg [1] -
3420:25
Hamburg-
Norderstedt [1] -
3420:25
hand [11] - 3473:2,
3473:23, 3499:5,
3508:4, 3544:13,
3552:5, 3563:9,
3567:10, 3567:11,
3569:5, 3572:4
handed [3] - 3571:4,
3589:5, 3589:14
handing [8] -
3511:15, 3534:23,
3541:1, 3555:1,
3575:2, 3581:23,
3592:19, 3594:9
handled [1] -
3422:11
hands [4] - 3387:24,
3444:17, 3480:1,
3567:19
happy [3] - 3386:18,
3555:17, 3632:12
hardly [4] - 3404:11,
3547:22, 3598:1,
3616:18
have.. [1] - 3414:16
HE [3] - 3565:7,
3565:25, 3566:6
head [2] - 3435:5,
3532:1
headed [1] - 3431:5
header [2] - 3545:17,
3552:19
heading [4] -
3448:13, 3501:23,
3513:3, 3550:18
Headquarters [1] -
3377:4
healing [1] - 3401:13
health [1] - 3413:15
hear [1] - 3419:12
heard [8] - 3394:24,
3397:14, 3401:18,
3446:24, 3448:1,
3448:2, 3555:5,
3611:6
hearing [1] - 3404:17
hearsay [6] -
3430:19, 3432:9,
3600:16, 3600:18,
3601:10, 3603:10
heart [2] - 3521:14,
3628:18
heavier [2] -

3458:24, 3515:25
heavily [1] - 3508:8
heavy [1] - 3579:12
heavy-weight [1] - 3579:12
heavyweight [7] - 3516:21, 3571:22, 3576:12, 3580:12, 3581:6, 3581:9, 3608:24
height [1] - 3573:22
Hellhammer [8] - 3430:2, 3430:4, 3430:5, 3432:25, 3436:18, 3437:12, 3439:17, 3439:21
Helmholtz [2] - 3391:2, 3391:10
help [12] - 3380:12, 3395:11, 3420:25, 3426:25, 3437:16, 3437:22, 3438:19, 3587:20, 3621:25, 3622:4, 3622:12, 3626:2
helped [4] - 3561:12, 3561:17, 3609:6, 3611:21
helpful [5] - 3393:1, 3395:24, 3442:19, 3548:25, 3550:19
helping [2] - 3406:24, 3444:13
hereby [1] - 3643:7
Hernia [13] - 3499:7, 3499:17, 3574:19, 3574:20, 3575:7, 3589:19, 3589:23, 3590:2, 3597:16, 3598:24, 3600:19, 3600:21, 3600:25
hernia [93] - 3382:17, 3382:21, 3382:22, 3385:18, 3403:9, 3457:13, 3488:10, 3490:14, 3490:15, 3497:19, 3497:23, 3498:4, 3498:9, 3498:19, 3498:21, 3499:1, 3499:2, 3499:12, 3500:5, 3500:6, 3501:10, 3501:17, 3502:25, 3504:7, 3505:2, 3505:24, 3506:6, 3506:25, 3514:17, 3515:13, 3519:18, 3519:19, 3521:22, 3522:22, 3523:6, 3523:13, 3525:15,

3526:14, 3526:24, 3527:3, 3527:8, 3528:6, 3528:7, 3528:11, 3528:17, 3528:25, 3529:16, 3529:18, 3530:16, 3532:4, 3544:24, 3551:18, 3564:23, 3566:20, 3569:10, 3578:6, 3578:21, 3589:16, 3589:24, 3590:1, 3590:4, 3590:18, 3595:22, 3597:14, 3597:15, 3597:18, 3597:24, 3598:17, 3601:18, 3603:3, 3613:10, 3613:24, 3614:21, 3620:17, 3620:18, 3620:23, 3628:16, 3629:15, 3629:21, 3629:24, 3630:3, 3632:21, 3633:12, 3633:13, 3633:19, 3633:24, 3634:10, 3634:15, 3638:22
hernias [8] - 3500:10, 3500:15, 3502:6, 3525:17, 3525:22, 3525:24, 3529:19, 3628:7
hernioplasty [3] - 3506:23, 3506:25, 3507:2
hi [1] - 3480:1
hiatal [1] - 3634:15
HIGBEE [1] - 3375:16
high [5] - 3546:16, 3548:17, 3578:7, 3587:19, 3617:18
higher [7] - 3442:18, 3454:12, 3524:2, 3559:3, 3559:8, 3599:16
highest [2] - 3449:14, 3624:9
Highland [1] - 3376:20
highlight [4] - 3490:1, 3511:8, 3549:14, 3586:21
highly [1] - 3398:9
hinder [1] - 3475:6
Hinoul [4] - 3409:6, 3409:10, 3412:5, 3412:21
Hinoul's [1] - 3450:25
histological [5] -

3395:12, 3396:9, 3583:10, 3583:21, 3585:20
Histological [1] - 3582:3
histology [6] - 3380:18, 3387:20, 3388:2, 3388:9, 3596:16
histopathological [1] - 3387:14
histopathologically [1] - 3601:19
histopathology [11] - 3387:18, 3392:10, 3395:2, 3395:4, 3395:6, 3397:5, 3401:12, 3402:15, 3404:24, 3405:6, 3491:7
historical [2] - 3431:1, 3431:5
Historical [2] - 3499:6, 3499:16
history [12] - 3400:2, 3400:3, 3442:25, 3490:10, 3498:19, 3498:21, 3498:24, 3499:1, 3512:18, 3522:22, 3528:6, 3528:16
hit [2] - 3555:16, 3613:5
hold [3] - 3402:18, 3402:20, 3430:3
holding [1] - 3567:18
hole [4] - 3424:25, 3506:14, 3605:5, 3606:4
holes [6] - 3422:12, 3424:24, 3452:22, 3452:25, 3464:12, 3604:9
Holste [4] - 3439:16, 3480:8, 3480:9, 3480:10
holy [2] - 3614:3, 3614:25
home [3] - 3485:10, 3582:18, 3582:20
Honor [56] - 3379:8, 3394:13, 3405:8, 3405:12, 3407:14, 3409:18, 3410:1, 3410:3, 3412:15, 3420:6, 3423:2, 3430:18, 3431:18, 3438:7, 3449:22, 3451:10, 3452:9, 3464:20, 3471:9,

3477:23, 3483:20, 3485:23, 3489:2, 3492:5, 3492:20, 3527:20, 3527:21, 3527:25, 3528:23, 3529:4, 3529:13, 3537:15, 3539:6, 3554:24, 3597:6, 3600:3, 3600:6, 3600:15, 3601:7, 3603:8, 3607:18, 3618:15, 3620:10, 3626:12, 3626:22, 3628:21, 3629:13, 3629:16, 3630:25, 3631:7, 3631:15, 3635:7, 3640:1, 3640:8, 3641:14, 3641:22
Honor's [2] - 3416:7, 3416:20
HONORABLE [1] - 3375:16
hope [2] - 3397:22, 3546:21
Hospital [2] - 3381:10, 3391:10
hospital [7] - 3381:10, 3381:12, 3384:2, 3390:4, 3391:8, 3393:12, 3402:5
hour [4] - 3406:20, 3406:21, 3492:7, 3528:15
hours [3] - 3406:23, 3528:4, 3600:24
HOUSTON [1] - 3376:9
huge [8] - 3442:15, 3445:6, 3455:3, 3458:14, 3520:23, 3529:11, 3575:23, 3616:16
Huge [1] - 3440:12
human [21] - 3385:15, 3388:15, 3395:2, 3397:2, 3399:7, 3400:20, 3404:25, 3405:7, 3420:11, 3423:19, 3441:9, 3485:3, 3497:16, 3520:12, 3545:25, 3586:13, 3587:15, 3602:2, 3605:4, 3621:11, 3637:24
humans [4] - 3394:7, 3448:22, 3454:23, 3570:6

humble [1] - 3404:15
hundreds [4] - 3381:15, 3386:12, 3406:7, 3524:16
HW [2] - 3579:13, 3580:12
hydroflow [1] - 3610:20
HYLAND [1] - 3377:3
i.e [1] - 3590:16
idea [8] - 3426:1, 3426:16, 3429:23, 3432:17, 3468:25, 3620:8, 3627:25, 3634:8
ideal [2] - 3534:21, 3546:18
identify [3] - 3424:5, 3610:2, 3610:4
IFU [9] - 3412:24, 3415:1, 3415:2, 3415:3, 3417:3, 3417:7, 3417:8, 3418:24, 3418:25
II [3] - 3517:3, 3575:16, 3576:13
III [3] - 3512:8, 3516:22, 3517:3
image [6] - 3446:2, 3454:14, 3455:5, 3470:4, 3478:19, 3583:22
image-based [1] - 3583:22
images [1] - 3386:12
imaginable [1] - 3534:22
imagine [2] - 3522:13, 3584:15
immediately [2] - 3444:9, 3551:8
impact [5] - 3392:25, 3393:3, 3393:6, 3507:14, 3598:2
implant [7] - 3382:2, 3454:18, 3470:24, 3519:14, 3594:5, 3595:16, 3605:17
implantation [7] - 3386:4, 3475:10, 3485:19, 3507:19, 3533:22, 3566:20, 3568:5
implanted [36] - 3388:16, 3391:23, 3397:7, 3402:16, 3404:5, 3411:2, 3416:11, 3428:12, 3428:17, 3428:24, 3434:12, 3441:20,

<p>3441:22, 3441:25, 3465:2, 3471:6, 3471:20, 3477:13, 3488:20, 3491:19, 3517:24, 3519:19, 3519:25, 3523:1, 3523:12, 3530:22, 3531:5, 3531:13, 3531:22, 3534:4, 3546:5, 3565:1, 3568:16, 3584:2, 3584:7, 3621:18 implanting [4] - 3454:22, 3510:12, 3532:15, 3579:16 implants [11] - 3392:20, 3395:12, 3484:22, 3527:11, 3552:20, 3552:25, 3587:21, 3595:6, 3622:14, 3636:6, 3636:10 implicating [1] - 3413:10 implications [1] - 3404:25 implicit [1] - 3415:15 importance [3] - 3481:1, 3564:21, 3599:10 important [20] - 3402:11, 3420:16, 3446:1, 3448:4, 3469:4, 3474:5, 3482:15, 3522:10, 3524:13, 3548:4, 3590:4, 3595:12, 3600:14, 3600:20, 3600:22, 3603:16, 3621:21, 3622:1, 3622:11, 3629:21 impossible [4] - 3444:21, 3630:8, 3632:19, 3633:5 impression [1] - 3476:24 improper [3] - 3417:6, 3471:1, 3471:21 improve [6] - 3426:23, 3427:11, 3427:12, 3431:16, 3453:19, 3587:20 improved [6] - 3396:6, 3435:24, 3435:25, 3437:21, 3505:3, 3507:15 improves [1] - 3421:4 inappropriate [1] -</p>	<p>3416:17 INC [2] - 3375:5, 3375:23 incidence [1] - 3550:7 incision [1] - 3517:4 incisional [1] - 3532:4 include [1] - 3532:18 included [2] - 3410:15, 3585:11 includes [2] - 3391:11, 3546:6 including [1] - 3380:18 income [1] - 3494:11 incontinence [3] - 3495:21, 3509:21, 3517:2 incorporate [1] - 3485:14 incorporated [2] - 3424:10, 3586:13 incorporation [3] - 3429:5, 3454:22, 3587:6 incorrect [1] - 3460:8 increase [4] - 3389:2, 3397:22, 3455:21, 3461:18 increased [5] - 3445:5, 3452:24, 3457:18, 3571:21, 3617:10 increasing [1] - 3382:24 increasingly [1] - 3383:2 indeed [2] - 3382:19, 3571:20 independent [2] - 3402:24, 3403:6 India [1] - 3524:21 indicate [3] - 3533:20, 3579:15, 3580:21 indicated [8] - 3420:9, 3529:25, 3530:22, 3537:25, 3538:25, 3540:9, 3616:25, 3625:13 indicating [4] - 3437:3, 3437:6, 3437:20, 3569:1 indication [7] - 3442:3, 3484:6, 3489:24, 3490:22, 3522:15, 3522:18, 3522:19</p>	<p>indications [4] - 3525:9, 3528:8, 3544:10, 3585:10 indicator [1] - 3621:17 individual [1] - 3534:10 individuals [2] - 3452:1, 3564:6 induce [3] - 3547:8, 3549:2, 3622:21 industry [1] - 3491:4 inert [2] - 3547:7, 3549:2 infection [6] - 3385:22, 3457:14, 3457:18, 3457:20, 3459:9, 3505:25 infections [1] - 3532:19 infiltrate [5] - 3444:24, 3446:13, 3458:9, 3610:22, 3641:1 infiltration [2] - 3595:13, 3603:16 INFINIT [2] - 3566:15, 3566:19 inflammation [14] - 3396:16, 3423:20, 3423:24, 3424:5, 3444:16, 3444:19, 3444:23, 3445:12, 3445:13, 3533:9, 3547:8, 3549:3, 3599:15, 3619:1 inflammatory [22] - 3426:10, 3444:24, 3445:22, 3446:13, 3456:19, 3458:9, 3533:21, 3566:7, 3566:16, 3582:3, 3583:6, 3583:10, 3585:20, 3602:19, 3604:5, 3611:1, 3615:6, 3619:4, 3622:16, 3622:22, 3622:23, 3640:25 influence [1] - 3575:11 information [12] - 3410:23, 3411:16, 3425:14, 3453:19, 3459:25, 3464:5, 3465:5, 3470:6, 3470:11, 3484:11, 3597:17, 3597:22 informs [2] - 3465:13, 3465:15 ingrowth [22] -</p>	<p>3479:1, 3588:4, 3588:11, 3588:15, 3588:16, 3594:3, 3595:15, 3602:16, 3602:24, 3604:10, 3604:24, 3605:7, 3605:12, 3605:13, 3605:16, 3606:11, 3606:13, 3606:14, 3606:17, 3606:18, 3609:18 inguinal [1] - 3505:24 initial [1] - 3533:21 initiate [1] - 3610:5 initiated [1] - 3481:9 injured [1] - 3444:7 injury [2] - 3388:5, 3388:7 inputs [1] - 3435:18 inside [10] - 3439:3, 3495:17, 3506:14, 3506:15, 3520:12, 3545:24, 3548:18, 3584:2, 3584:7, 3587:15 instance [2] - 3442:8, 3614:21 instead [4] - 3457:7, 3511:12, 3553:15, 3632:9 institute [1] - 3618:5 Institute [3] - 3391:2, 3391:10, 3560:4 institutes [3] - 3381:5, 3391:11, 3393:12 instruments [1] - 3579:20 integrated [6] - 3386:8, 3393:15, 3429:7, 3444:19, 3446:20, 3455:16 integration [9] - 3421:4, 3455:14, 3566:7, 3566:17, 3578:8, 3595:14, 3603:17, 3611:5, 3638:25 Integration [1] - 3545:18 integrative [1] - 3387:15 intend [3] - 3410:5, 3477:15, 3620:14 intended [4] - 3476:19, 3616:6, 3617:18, 3617:19 intending [1] - 3409:23</p>	<p>intensive [4] - 3389:16, 3389:19, 3389:22, 3389:23 intent [4] - 3413:23, 3415:22, 3416:1, 3617:2 intention [1] - 3616:23 interactions [3] - 3430:25, 3431:6, 3432:1 interconnect [1] - 3553:25 interested [1] - 3480:3 interesting [1] - 3479:17 interface [1] - 3423:21 internal [8] - 3384:6, 3384:23, 3406:4, 3452:18, 3491:10, 3541:3, 3541:6, 3641:11 International [2] - 3508:23, 3535:2 international [1] - 3597:21 interpretation [2] - 3466:4, 3598:5 interrupting [1] - 3383:6 interstices [1] - 3553:2 intervals [2] - 3517:9, 3517:21 interview [1] - 3562:21 intra [1] - 3575:11 intra-abdominal [1] - 3575:11 intraoperative [1] - 3551:7 introduced [2] - 3503:17, 3505:3 introduction [1] - 3504:21 invader [1] - 3444:5 Invasive [2] - 3564:7, 3564:11 invent [2] - 3561:12, 3561:17 invented [2] - 3437:19, 3561:11 invention [1] - 3473:15 inventor [2] - 3435:1, 3435:21 investigate [2] - 3587:19, 3621:12</p>
--	--	---	---	--

<p>investigated [1] - 3576:2</p> <p>investigations [3] - 3387:16, 3394:9, 3394:19</p> <p>investigator [3] - 3388:19, 3391:16, 3392:8</p> <p>investigators [1] - 3480:11</p> <p>invited [6] - 3398:22, 3399:2, 3399:18, 3399:21, 3400:4, 3439:7</p> <p>involve [2] - 3387:13, 3540:22</p> <p>involved [5] - 3402:13, 3412:2, 3429:25, 3525:16, 3542:15</p> <p>involving [3] - 3380:22, 3398:16, 3638:12</p> <p>irregular [2] - 3463:8, 3469:16</p> <p>issue [11] - 3393:7, 3409:23, 3410:2, 3414:22, 3414:23, 3416:23, 3430:22, 3574:19, 3574:20, 3583:6</p> <p>issues [7] - 3380:21, 3398:15, 3399:5, 3413:11, 3415:21, 3491:5, 3530:8</p> <p>it's... [1] - 3389:13</p> <p>itself [4] - 3423:2, 3423:8, 3461:14, 3631:13</p> <p>Jacob [1] - 3600:25</p> <p>Jacquetin [2] - 3435:18, 3435:20</p> <p>Jamey [30] - 3499:11, 3499:13, 3499:23, 3499:25, 3506:4, 3507:22, 3509:16, 3512:5, 3539:11, 3542:4, 3550:16, 3555:3, 3556:6, 3563:19, 3565:6, 3566:12, 3566:25, 3567:16, 3567:25, 3568:22, 3569:6, 3569:20, 3570:23, 3575:14, 3578:3, 3578:11, 3585:25, 3594:12, 3595:3, 3596:7</p> <p>Jan [4] - 3603:14, 3607:13, 3622:13,</p>	<p>3623:1</p> <p>January [1] - 3511:9</p> <p>JEFFREY [2] - 3375:3, 3376:14</p> <p>Jennifer [1] - 3490:5</p> <p>JERSEY [1] - 3375:1</p> <p>Jersey [5] - 3375:10, 3376:5, 3377:5, 3427:23, 3643:7</p> <p>job [4] - 3410:6, 3431:2, 3538:12, 3601:1</p> <p>Joerg [3] - 3480:8, 3480:9, 3480:10</p> <p>JOHN [1] - 3375:6</p> <p>Johnson [2] - 3376:23</p> <p>JOHNSON [2] - 3375:5, 3375:6</p> <p>join [2] - 3409:20, 3543:13</p> <p>JONES [5] - 3376:19, 3409:7, 3410:1, 3412:12, 3418:5</p> <p>Jones [1] - 3409:23</p> <p>Josh [1] - 3623:21</p> <p>Joshua [1] - 3543:5</p> <p>Journal [5] - 3508:24, 3535:3, 3582:8, 3582:12, 3582:19</p> <p>journal [10] - 3509:1, 3511:20, 3511:25, 3535:6, 3582:12, 3582:18, 3590:4, 3600:19, 3600:21</p> <p>journals [3] - 3400:23, 3400:25, 3401:4</p> <p>judge [1] - 3410:16</p> <p>Judge [5] - 3410:22, 3412:20, 3519:7, 3537:19, 3554:6</p> <p>Judicial [1] - 3643:9</p> <p>Juergen [1] - 3480:16</p> <p>July [1] - 3434:23</p> <p>June [6] - 3434:23, 3439:4, 3439:14, 3449:3, 3453:11, 3469:10</p> <p>jurors [1] - 3408:8</p> <p>jury [99] - 3379:2, 3379:4, 3379:24, 3380:8, 3380:10, 3380:22, 3387:17, 3388:21, 3390:8, 3392:15, 3395:3, 3397:14, 3401:18, 3404:4, 3404:17,</p>	<p>3405:10, 3407:17, 3408:3, 3408:12, 3408:16, 3408:18, 3408:21, 3415:3, 3419:12, 3420:3, 3420:9, 3420:21, 3421:22, 3422:11, 3424:2, 3427:22, 3429:15, 3431:18, 3432:24, 3434:22, 3438:25, 3441:7, 3442:23, 3444:4, 3445:22, 3446:24, 3448:1, 3448:4, 3452:6, 3452:21, 3454:5, 3457:2, 3457:6, 3458:23, 3459:24, 3460:24, 3463:16, 3466:22, 3469:21, 3469:24, 3474:14, 3476:16, 3479:15, 3484:9, 3487:22, 3489:13, 3492:9, 3492:15, 3492:17, 3506:18, 3518:19, 3519:10, 3554:13, 3554:18, 3554:20, 3555:3, 3555:5, 3555:9, 3556:14, 3556:25, 3571:9, 3599:4, 3601:15, 3603:20, 3607:25, 3611:6, 3612:7, 3614:13, 3615:18, 3618:25, 3619:25, 3620:13, 3620:14, 3623:18, 3624:6, 3625:9, 3628:4, 3635:19, 3637:2, 3639:4, 3641:19, 3641:23, 3642:1</p> <p>jury's [2] - 3420:16, 3453:24</p> <p>justifiably [1] - 3507:17</p> <p>justified [1] - 3639:24</p> <p>KATZ [1] - 3376:3</p> <p>kcrawford@riker.com [1] - 3377:6</p> <p>keep [6] - 3481:22, 3529:10, 3548:22, 3548:23, 3591:18, 3613:25</p> <p>keeps [2] - 3528:23, 3551:1</p> <p>KELLY [1] - 3377:3</p> <p>kept [2] - 3412:23, 3587:8</p>	<p>kill [2] - 3526:11, 3526:12</p> <p>killed [1] - 3615:10</p> <p>kilogram [2] - 3474:21, 3475:15</p> <p>kilograms [1] - 3483:15</p> <p>kind [22] - 3394:14, 3494:3, 3494:7, 3495:20, 3496:16, 3499:22, 3506:15, 3535:14, 3535:16, 3536:17, 3541:23, 3546:2, 3551:15, 3555:16, 3558:9, 3568:1, 3572:25, 3580:13, 3581:13, 3586:9, 3595:9, 3628:16</p> <p>kinds [2] - 3528:18, 3619:23</p> <p>Kingsnorth [1] - 3523:17</p> <p>Kirsten [2] - 3452:2, 3629:19</p> <p>KLINGE [2] - 3378:5, 3379:11</p> <p>Klinge [37] - 3379:9, 3379:16, 3379:22, 3380:10, 3381:25, 3405:4, 3420:9, 3423:15, 3424:17, 3425:15, 3428:10, 3429:11, 3429:15, 3434:19, 3437:16, 3438:23, 3440:16, 3446:6, 3449:7, 3453:14, 3454:11, 3472:14, 3480:25, 3485:19, 3487:2, 3489:12, 3490:13, 3492:25, 3540:13, 3555:1, 3555:5, 3556:8, 3595:25, 3596:10, 3597:11, 3607:22, 3608:13</p> <p>Klinge's [4] - 3459:25, 3566:25, 3586:1</p> <p>Klosterhalfen [10] - 3395:18, 3440:2, 3440:9, 3443:15, 3447:19, 3448:23, 3545:3, 3601:19, 3607:22, 3638:15</p> <p>knee [1] - 3544:11</p> <p>knit [1] - 3553:22</p> <p>knitted [6] - 3505:4, 3505:11, 3553:3, 3553:9, 3553:10,</p>	<p>3622:15</p> <p>Knitted [2] - 3553:20, 3553:21</p> <p>knots [2] - 3458:17, 3553:16</p> <p>knotting [2] - 3458:4, 3553:1</p> <p>knowledge [7] - 3396:6, 3415:18, 3417:12, 3427:8, 3453:23, 3467:8, 3643:10</p> <p>known [8] - 3395:18, 3414:1, 3419:3, 3419:4, 3451:8, 3533:19, 3547:8, 3549:3</p> <p>knows [5] - 3395:22, 3418:23, 3418:25, 3423:8</p> <p>Kockerling [1] - 3600:25</p> <p>lab [1] - 3389:2</p> <p>label [1] - 3409:16</p> <p>lack [2] - 3450:11, 3450:13</p> <p>lacking [2] - 3627:13, 3627:15</p> <p>language [2] - 3573:2, 3640:4</p> <p>laparoscopic [6] - 3506:5, 3506:6, 3506:19, 3506:21, 3532:4, 3569:10</p> <p>laparoscopically [2] - 3506:24, 3507:5</p> <p>large [32] - 3393:11, 3421:15, 3425:17, 3425:21, 3427:18, 3433:8, 3446:14, 3448:1, 3448:5, 3455:10, 3459:1, 3459:4, 3460:10, 3460:14, 3483:5, 3525:5, 3544:24, 3565:1, 3583:11, 3590:23, 3590:24, 3596:22, 3598:8, 3599:17, 3608:3, 3609:1, 3609:5, 3613:8, 3613:14, 3623:5, 3623:6, 3627:22</p> <p>larger [24] - 3422:4, 3422:7, 3422:11, 3454:17, 3473:20, 3538:6, 3538:23, 3539:3, 3539:17, 3539:18, 3539:25, 3540:1, 3556:22,</p>
---	---	---	---	--

3557:19, 3557:22,
3591:1, 3591:14,
3592:1, 3602:17,
3606:20, 3607:15,
3608:21, 3613:22,
3616:16
Larger [2] - 3606:21,
3607:7
last [27] - 3379:15,
3394:22, 3398:5,
3399:21, 3404:19,
3424:10, 3431:21,
3440:3, 3443:8,
3454:5, 3460:24,
3472:9, 3472:12,
3490:1, 3560:1,
3562:8, 3587:4,
3587:12, 3594:1,
3600:12, 3600:24,
3613:2, 3620:13,
3633:10, 3635:1,
3635:20
late [4] - 3458:22,
3460:3, 3512:22,
3513:6
latter [1] - 3630:8
launch [5] - 3429:13,
3429:21, 3437:19,
3438:15, 3439:12
launched [9] -
3437:1, 3437:6,
3466:13, 3467:12,
3468:22, 3469:11,
3482:19, 3484:15,
3515:1
launching [4] -
3453:24, 3462:14,
3463:18, 3488:18
LAW [1] - 3376:9
law [1] - 3427:23
lawsuit [1] - 3525:16
lawyer [1] - 3493:3
lay [4] - 3520:15,
3543:18, 3623:22,
3632:2
layer [1] - 3632:13
laying [6] - 3487:19,
3605:3, 3630:18,
3631:18, 3632:7,
3632:9
lead [5] - 3425:1,
3435:23, 3452:20,
3460:18, 3595:25
leader [1] - 3388:24
leading [10] - 3382:2,
3427:3, 3479:7,
3479:9, 3483:20,
3487:16, 3489:2,
3602:11, 3609:7,
3641:15

leads [3] - 3429:4,
3456:24, 3551:12
learn [4] - 3388:6,
3462:12, 3521:14,
3641:1
learned [5] -
3381:14, 3410:20,
3417:22, 3418:2,
3597:19
least [18] - 3383:21,
3393:25, 3406:6,
3406:12, 3414:18,
3417:9, 3447:9,
3448:9, 3464:8,
3514:13, 3526:14,
3558:10, 3559:25,
3574:1, 3574:23,
3593:1, 3593:16
leather [2] - 3448:15,
3449:1
leave [1] - 3462:6
leaves [4] - 3408:21,
3492:9, 3554:13,
3642:1
leaving [1] - 3555:14
lecture [3] - 3400:4,
3400:10, 3498:21
lectured [1] - 3399:1
lecturer [2] -
3398:22, 3399:2
lectures [2] - 3384:2,
3399:4
leeway [1] - 3419:17
left [8] - 3435:10,
3436:20, 3454:4,
3482:10, 3482:11,
3487:4, 3595:4,
3631:2
legendi [6] -
3383:25, 3384:9,
3385:12, 3387:2,
3387:13
legitimately [1] -
3530:7
lengthy [1] - 3542:4
less [13] - 3424:12,
3452:19, 3462:8,
3483:13, 3520:21,
3547:18, 3570:14,
3591:23, 3613:5,
3615:6, 3623:15,
3638:18, 3639:8
letter [3] - 3468:5,
3600:6, 3600:16
letters [2] - 3563:15,
3600:9
letting [1] - 3579:17
level [9] - 3385:12,
3387:23, 3543:22,
3543:23, 3548:11,

3548:17, 3549:7,
3624:4, 3624:15
License [1] - 3643:5
lie [1] - 3484:22
LIEBHARD [1] -
3376:14
life [4] - 3442:10,
3468:18, 3485:11,
3621:19
lifelong [2] -
3423:25, 3445:3
ligament [1] -
3544:11
ligaments [1] -
3476:23
light [9] - 3558:3,
3558:6, 3571:2,
3571:13, 3571:14,
3571:15, 3589:25,
3638:17
lighter [2] - 3608:20,
3613:21
Lightning [3] -
3611:11, 3612:24,
3613:3
lightweight [14] -
3425:17, 3425:20,
3459:5, 3544:24,
3563:11, 3563:22,
3565:1, 3569:11,
3569:24, 3570:13,
3581:7, 3609:1,
3609:5, 3623:6
likely [2] - 3516:10,
3613:6
limit [9] - 3455:17,
3528:3, 3529:20,
3596:15, 3605:6,
3606:21, 3607:7,
3612:11, 3618:8
limitation [1] -
3553:14
limitations [2] -
3597:20, 3634:13
limited [2] - 3586:25,
3630:21
Lin [2] - 3465:13,
3465:15
LINDA [1] - 3375:3
Linda [3] - 3411:2,
3416:10, 3450:6
Linda's [1] - 3413:20
line [15] - 3411:8,
3440:10, 3443:12,
3457:25, 3458:1,
3467:23, 3536:19,
3536:24, 3555:19,
3601:4, 3601:5,
3607:5, 3614:17,
3615:8, 3619:18

lines [1] - 3619:24
liquid [1] - 3385:21
list [2] - 3384:5,
3462:21
listed [5] - 3561:25,
3562:1, 3598:18,
3599:1, 3599:11
listen [1] - 3431:23
listing [1] - 3462:23
literature [27] -
3384:21, 3397:15,
3397:17, 3397:20,
3398:7, 3401:2,
3401:9, 3406:10,
3409:18, 3409:24,
3410:5, 3414:10,
3414:13, 3414:15,
3417:17, 3417:19,
3419:5, 3419:19,
3442:16, 3452:18,
3460:2, 3460:6,
3460:12, 3471:14,
3475:3, 3535:17,
3537:20
Literature [2] -
3549:13, 3585:5
litigation [1] -
3615:17
live [2] - 3379:25,
3565:11
liver [1] - 3390:16
lives [1] - 3507:15
living [3] - 3380:1,
3380:5, 3457:11
LLC [2] - 3376:3,
3376:9
LLP [2] - 3376:14,
3377:3
load [10] - 3475:15,
3476:6, 3476:9,
3477:7, 3477:17,
3478:12, 3482:13,
3482:16, 3484:6,
3529:1
local [2] - 3444:11,
3604:5
location [1] - 3534:9
long-term [4] -
3627:3, 3627:13,
3627:14, 3627:22
look [65] - 3383:13,
3385:6, 3387:16,
3388:1, 3388:8,
3394:6, 3395:9,
3396:9, 3404:8,
3434:16, 3442:1,
3447:23, 3448:24,
3453:8, 3458:5,
3459:5, 3459:7,
3462:16, 3470:3,

3472:21, 3473:2,
3474:8, 3475:16,
3477:5, 3477:18,
3478:2, 3489:7,
3489:9, 3495:10,
3501:14, 3501:19,
3501:21, 3504:17,
3506:14, 3510:2,
3512:24, 3524:24,
3525:2, 3537:8,
3540:9, 3541:2,
3543:17, 3563:15,
3565:19, 3569:20,
3572:6, 3572:9,
3575:24, 3582:7,
3596:6, 3602:25,
3607:14, 3613:3,
3614:14, 3618:13,
3618:18, 3624:23,
3631:17, 3639:20,
3640:20, 3640:24,
3641:10
looked [23] - 3396:6,
3396:7, 3398:5,
3406:4, 3406:17,
3411:22, 3468:24,
3477:9, 3477:11,
3500:14, 3502:5,
3530:23, 3534:25,
3537:5, 3541:6,
3541:12, 3557:17,
3563:3, 3570:5,
3576:1, 3602:2,
3602:3, 3624:21
looking [57] -
3386:3, 3386:4,
3386:6, 3388:14,
3392:9, 3394:25,
3396:19, 3401:1,
3410:11, 3439:6,
3446:7, 3448:25,
3449:4, 3449:5,
3451:24, 3456:10,
3456:17, 3459:9,
3460:20, 3462:25,
3463:18, 3463:22,
3466:14, 3466:21,
3481:1, 3482:2,
3489:6, 3491:5,
3502:19, 3502:25,
3510:7, 3524:20,
3535:21, 3542:8,
3546:17, 3563:23,
3571:2, 3572:25,
3575:19, 3577:2,
3579:19, 3581:5,
3581:6, 3599:7,
3602:8, 3611:8,
3611:12, 3611:15,
3611:18, 3612:4,
3613:21, 3614:11,

3616:17, 3629:10,
3640:21
looks [3] - 3577:7,
3577:21, 3621:20
loosening [1] -
3554:2
Los [1] - 3457:11
lose [1] - 3617:17
losing [1] - 3453:1
lost [1] - 3607:16
love [1] - 3530:4
low [12] - 3487:25,
3489:23, 3527:13,
3527:19, 3578:20,
3579:6, 3579:8,
3580:13, 3581:9,
3626:6, 3640:23
low-weight [2] -
3578:20, 3579:6
lower [7] - 3422:7,
3457:20, 3538:7,
3570:15, 3586:8,
3634:17, 3638:19
lowered [1] -
3435:25
lowest [2] - 3581:16,
3624:15
LP [5] - 3563:12,
3563:22, 3565:2,
3566:14, 3621:15
LT266.3 [1] - 3545:14
LT647.7 [1] - 3499:21
LT647.8 [1] - 3504:3
lunch [2] - 3486:14,
3492:6
lungs [1] - 3628:18
LW [2] - 3579:7,
3580:14
lying [1] - 3488:13
ma'am [2] - 3438:11,
3635:13
machine [4] -
3472:21, 3473:3,
3475:20, 3476:4
macrophages [6] -
3547:23, 3549:8,
3592:3, 3604:16,
3605:25, 3606:2
Macroporous [1] -
3574:4
macroporous [8] -
3448:2, 3574:6,
3574:12, 3574:23,
3590:21, 3590:22,
3591:1, 3591:5
magically [1] -
3487:15
magnification [1] -
3454:13
mail [20] - 3431:23,

3434:23, 3435:7,
3435:12, 3435:16,
3436:20, 3437:18,
3465:7, 3469:10,
3473:24, 3480:7,
3480:17, 3484:9,
3484:11, 3541:3,
3603:7, 3603:11,
3623:20, 3636:9
mailed [1] - 3582:17
mailing [1] - 3542:20
mails [7] - 3434:19,
3436:5, 3436:17,
3439:15, 3449:10,
3543:10, 3625:11
main [6] - 3381:4,
3391:7, 3426:20,
3435:22, 3448:8,
3456:6
major [7] - 3381:12,
3390:18, 3421:25,
3449:9, 3500:23,
3507:6, 3598:9
maker [1] - 3559:15
male [1] - 3580:5
man [1] - 3530:6
manner [2] -
3464:10, 3598:23
manual [1] - 3465:16
manuals [1] -
3409:14
manufacture [1] -
3552:24
manufactured [1] -
3559:10
manufacturer [1] -
3612:19
manufacturers [8] -
3392:13, 3392:17,
3425:10, 3427:1,
3427:8, 3598:9,
3598:13, 3599:22
manuscript [1] -
3612:13
manuscripts [1] -
3401:5
March [12] - 3429:13,
3429:22, 3463:23,
3467:12, 3468:8,
3468:22, 3473:7,
3477:4, 3488:19,
3491:18, 3491:25,
3627:17
Margolis [1] -
3416:19
MARIE [3] - 3375:23,
3643:4, 3643:15
marked [2] -
3534:24, 3575:2
markers [2] -

3395:23, 3395:24
market [7] - 3450:15,
3483:3, 3533:20,
3543:3, 3571:19,
3593:24, 3627:17
marketed [1] -
3505:7
marks [1] - 3566:3
Marlex [16] -
3503:18, 3504:8,
3505:3, 3505:8,
3509:13, 3509:18,
3509:23, 3510:7,
3510:12, 3510:24,
3511:11, 3529:2,
3529:6, 3530:22,
3591:10, 3591:11
Marty [1] - 3480:1
Massachusetts [1] -
3505:7
matched [1] - 3614:4
Material [1] -
3640:20
material [42] -
3393:2, 3393:3,
3393:7, 3393:22,
3421:12, 3422:7,
3440:13, 3440:17,
3440:19, 3441:4,
3443:17, 3443:24,
3449:13, 3451:24,
3461:15, 3475:11,
3481:9, 3500:23,
3501:10, 3501:16,
3503:20, 3505:6,
3512:21, 3513:6,
3514:12, 3520:24,
3521:7, 3521:22,
3521:25, 3529:25,
3530:2, 3530:3,
3539:14, 3558:21,
3563:24, 3581:15,
3589:10, 3597:23,
3611:18, 3614:9,
3631:13, 3631:14
Materials [3] -
3511:7, 3583:15,
3585:6
materials [32] -
3388:10, 3392:21,
3392:24, 3392:25,
3393:23, 3395:7,
3395:13, 3395:25,
3396:1, 3405:23,
3406:1, 3423:18,
3427:12, 3435:17,
3439:6, 3457:16,
3491:8, 3500:15,
3525:9, 3528:8,
3537:21, 3547:7,

3549:2, 3553:5,
3568:24, 3597:24,
3598:4, 3601:22,
3615:1, 3622:21,
3622:23, 3633:8
math [1] - 3573:16
mathematical [1] -
3585:18
matter [4] - 3481:15,
3481:17, 3524:25,
3525:1
matures [1] - 3453:1
maturing [1] -
3429:6
MAZIE [15] - 3376:3,
3376:3, 3409:6,
3409:11, 3409:17,
3410:16, 3410:21,
3411:19, 3415:11,
3415:14, 3416:3,
3417:15, 3418:16,
3450:25, 3538:9
Mazie [1] - 3528:2
mean [54] - 3383:25,
3384:11, 3390:6,
3396:8, 3404:13,
3411:1, 3411:14,
3412:3, 3413:9,
3414:1, 3415:15,
3415:23, 3416:18,
3417:25, 3419:11,
3419:14, 3421:6,
3422:20, 3434:11,
3455:20, 3466:2,
3474:2, 3488:9,
3493:17, 3500:9,
3501:4, 3513:17,
3514:21, 3517:1,
3517:9, 3517:21,
3529:18, 3536:16,
3536:18, 3546:22,
3547:17, 3548:10,
3548:16, 3555:24,
3557:13, 3563:17,
3565:22, 3579:8,
3582:18, 3589:23,
3589:25, 3590:1,
3594:24, 3616:8,
3622:18, 3623:4,
3628:10, 3628:16,
3631:22
meaning [3] -
3543:23, 3604:18,
3624:22
meaningless [1] -
3458:21
means [30] -
3381:22, 3384:15,
3390:9, 3390:13,
3390:14, 3397:15,

3421:13, 3429:6,
3440:21, 3444:23,
3455:9, 3461:16,
3463:2, 3463:3,
3474:21, 3476:8,
3481:11, 3482:20,
3496:5, 3510:11,
3517:22, 3517:24,
3536:19, 3549:6,
3551:1, 3553:17,
3574:8, 3576:15,
3599:16, 3605:22
meant [2] - 3548:7,
3548:9
meanwhile [6] -
3427:18, 3448:22,
3448:23, 3459:16,
3590:6, 3597:23
measure [16] -
3426:2, 3458:5,
3458:18, 3463:1,
3463:14, 3463:25,
3466:2, 3466:5,
3469:7, 3469:8,
3470:8, 3473:25,
3479:18, 3483:6,
3599:6, 3636:25
measured [7] -
3466:8, 3466:17,
3469:12, 3469:14,
3473:8, 3479:21,
3587:6
measurement [4] -
3463:9, 3479:21,
3555:24, 3596:21
measurements [2] -
3473:15, 3573:17
measuring [6] -
3463:23, 3465:7,
3465:10, 3465:16,
3465:25, 3467:13
mechanical [12] -
3429:4, 3476:6,
3477:1, 3477:7,
3477:17, 3482:13,
3482:16, 3489:18,
3595:14, 3603:17,
3617:20, 3632:6
median [2] -
3536:21, 3536:23
medical [22] -
3380:12, 3380:25,
3381:8, 3383:11,
3389:25, 3390:2,
3391:8, 3392:12,
3392:16, 3394:11,
3409:24, 3413:25,
3427:25, 3428:3,
3472:13, 3495:3,
3497:4, 3593:17,

3593:18, 3593:21,
3595:1, 3635:3
Medicine [1] -
3593:5
medicine [4] -
3389:16, 3389:23,
3391:13, 3529:12
medium [5] - 3565:3,
3569:11, 3570:1,
3570:17, 3576:15
medium-weight [3] -
3569:11, 3570:1,
3570:17
meet [3] - 3441:19,
3469:22, 3493:4
meeting [17] -
3432:25, 3436:17,
3437:11, 3439:1,
3439:3, 3439:5,
3440:8, 3447:22,
3449:3, 3449:18,
3450:5, 3451:7,
3451:22, 3452:3,
3453:10, 3629:12,
3629:19
meetings [9] -
3393:25, 3424:22,
3429:17, 3429:21,
3432:16, 3432:20,
3439:20, 3439:23,
3534:14
member [1] - 3435:4
members [3] -
3466:4, 3466:18,
3473:25
mention [1] - 3563:4
mentioned [11] -
3395:2, 3396:18,
3407:2, 3432:7,
3458:23, 3483:7,
3518:14, 3518:16,
3523:18, 3540:16,
3561:16
mentioning [1] -
3498:22
mentions [1] -
3444:2
Mesh [6] - 3466:20,
3469:13, 3499:22,
3512:12, 3515:1,
3515:5
mesh [324] - 3382:4,
3382:8, 3396:23,
3398:16, 3399:5,
3402:14, 3402:22,
3404:5, 3407:16,
3408:9, 3420:20,
3420:23, 3421:2,
3421:7, 3421:8,
3421:14, 3421:16,

3421:17, 3421:18,
3422:7, 3422:12,
3422:13, 3422:17,
3422:18, 3422:21,
3423:2, 3423:3,
3423:10, 3423:11,
3424:8, 3424:9,
3424:18, 3425:1,
3426:11, 3426:19,
3427:11, 3427:12,
3428:25, 3429:7,
3429:23, 3433:8,
3433:22, 3435:9,
3435:10, 3435:17,
3435:23, 3436:1,
3439:9, 3440:11,
3441:2, 3442:9,
3442:24, 3443:9,
3443:13, 3443:18,
3443:23, 3443:25,
3445:3, 3446:7,
3448:13, 3448:17,
3452:17, 3453:3,
3453:20, 3454:1,
3454:12, 3455:6,
3455:23, 3456:16,
3457:16, 3458:12,
3458:13, 3458:16,
3461:22, 3464:3,
3464:5, 3465:16,
3465:19, 3466:1,
3466:7, 3466:18,
3466:19, 3468:14,
3470:2, 3470:7,
3471:1, 3471:4,
3471:20, 3471:22,
3475:2, 3476:8,
3476:11, 3477:7,
3477:15, 3478:11,
3479:4, 3479:18,
3481:8, 3481:14,
3481:24, 3485:11,
3488:8, 3488:10,
3489:15, 3490:6,
3490:14, 3495:6,
3495:9, 3495:13,
3495:16, 3496:10,
3496:18, 3496:21,
3496:24, 3498:24,
3499:19, 3500:4,
3500:5, 3500:9,
3500:10, 3503:11,
3503:18, 3503:20,
3503:21, 3504:8,
3504:20, 3505:4,
3505:8, 3505:12,
3505:15, 3505:23,
3506:8, 3506:13,
3507:1, 3507:13,
3507:18, 3509:13,
3509:18, 3509:24,

3510:12, 3510:24,
3511:11, 3512:2,
3512:8, 3512:11,
3513:5, 3514:17,
3514:19, 3515:10,
3515:12, 3515:13,
3515:18, 3516:2,
3516:4, 3516:17,
3516:21, 3517:5,
3517:12, 3517:23,
3518:7, 3518:17,
3518:20, 3519:6,
3519:14, 3519:19,
3520:14, 3520:18,
3521:6, 3521:18,
3521:21, 3521:24,
3522:10, 3522:15,
3526:21, 3527:11,
3530:22, 3531:1,
3531:3, 3531:6,
3531:8, 3531:22,
3532:5, 3532:25,
3533:3, 3533:20,
3534:5, 3534:16,
3534:18, 3534:21,
3537:5, 3538:7,
3540:10, 3543:17,
3543:19, 3544:4,
3544:24, 3545:24,
3546:5, 3546:18,
3547:24, 3548:18,
3550:8, 3550:12,
3550:13, 3550:14,
3551:25, 3552:22,
3553:22, 3554:2,
3557:11, 3557:17,
3557:21, 3557:25,
3558:16, 3558:17,
3558:19, 3558:25,
3559:6, 3559:7,
3559:15, 3559:23,
3559:25, 3561:4,
3561:14, 3563:11,
3563:22, 3563:23,
3564:16, 3565:2,
3565:3, 3565:18,
3565:19, 3568:3,
3568:5, 3568:24,
3569:11, 3569:12,
3569:18, 3569:24,
3570:1, 3570:14,
3570:17, 3571:17,
3571:19, 3574:8,
3576:12, 3578:21,
3579:7, 3579:12,
3579:16, 3579:19,
3581:6, 3581:7,
3581:9, 3581:15,
3582:4, 3583:7,
3583:11, 3583:19,
3583:20, 3584:2,

3584:6, 3584:23,
3586:13, 3591:7,
3591:8, 3597:24,
3598:4, 3604:9,
3605:4, 3612:2,
3613:10, 3613:22,
3613:24, 3614:16,
3615:1, 3616:16,
3621:18, 3621:21,
3621:22, 3623:10,
3623:14, 3623:22,
3623:24, 3625:3,
3627:21, 3628:15,
3629:4, 3629:5,
3630:3, 3630:4,
3630:11, 3630:13,
3630:16, 3630:22,
3631:1, 3631:18,
3631:22, 3632:2,
3632:13, 3632:18,
3632:19, 3633:2,
3633:13, 3633:22,
3634:11, 3634:17,
3634:18, 3634:25,
3636:13, 3636:16,
3636:17, 3637:6,
3638:18, 3638:23
meshes [131] -
3380:19, 3382:25,
3383:2, 3383:21,
3385:15, 3385:18,
3387:11, 3387:19,
3388:15, 3388:16,
3388:24, 3391:23,
3394:7, 3395:1,
3396:20, 3397:7,
3397:9, 3397:24,
3398:6, 3400:2,
3400:3, 3400:5,
3400:10, 3400:19,
3402:15, 3404:8,
3404:21, 3404:25,
3405:7, 3420:11,
3421:9, 3421:25,
3422:3, 3422:4,
3426:2, 3426:5,
3426:9, 3427:1,
3427:18, 3431:12,
3432:18, 3433:4,
3436:7, 3440:12,
3441:13, 3442:12,
3442:13, 3442:17,
3443:20, 3446:1,
3448:22, 3452:19,
3457:13, 3458:24,
3459:1, 3459:5,
3459:16, 3466:10,
3476:25, 3481:2,
3483:10, 3491:6,
3499:2, 3500:19,
3519:18, 3519:25,

3522:2, 3522:18,
3523:1, 3523:2,
3523:12, 3523:18,
3524:5, 3525:4,
3525:5, 3525:14,
3526:24, 3532:9,
3532:15, 3534:2,
3540:17, 3546:20,
3553:3, 3556:11,
3558:14, 3560:8,
3561:11, 3561:12,
3561:23, 3562:23,
3565:9, 3565:22,
3566:7, 3566:19,
3568:18, 3569:23,
3571:20, 3571:22,
3574:17, 3575:20,
3576:2, 3577:1,
3580:10, 3590:16,
3591:1, 3591:2,
3595:22, 3595:23,
3598:7, 3598:8,
3598:17, 3598:19,
3599:17, 3599:23,
3603:4, 3608:21,
3608:24, 3609:2,
3611:1, 3611:2,
3612:12, 3614:4,
3621:24, 3631:6,
3633:20, 3639:17
message [4] -
3426:20, 3448:8,
3449:11, 3460:10
messages [1] -
3436:8
met [1] - 3623:1
metal [1] - 3503:21
meters [9] - 3391:18,
3440:13, 3440:21,
3443:16, 3520:19,
3520:20, 3520:21,
3521:2, 3521:3
method [6] -
3466:10, 3466:14,
3467:19, 3467:22,
3469:15, 3557:15
Methods [7] -
3511:7, 3517:1,
3564:25, 3569:21,
3583:15, 3585:6,
3640:20
methods [4] -
3468:7, 3468:12,
3468:16, 3468:24
Michel [5] - 3434:23,
3434:25, 3543:14,
3623:21, 3625:3
microns [65] -
3457:3, 3457:7,
3457:9, 3457:19,

3457:21, 3457:22,
3457:24, 3457:25,
3458:3, 3458:7,
3458:16, 3469:12,
3556:25, 3557:2,
3557:5, 3557:7,
3573:3, 3573:8,
3573:13, 3573:14,
3573:19, 3574:1,
3574:23, 3576:10,
3588:5, 3588:11,
3588:20, 3588:22,
3588:23, 3589:1,
3589:8, 3591:15,
3591:17, 3591:20,
3591:22, 3591:24,
3592:2, 3594:3,
3595:15, 3596:15,
3596:16, 3597:3,
3598:18, 3602:23,
3603:19, 3604:4,
3604:6, 3604:8,
3604:10, 3604:14,
3604:20, 3604:25,
3605:3, 3605:24,
3606:5, 3606:12,
3608:9, 3608:12,
3609:17, 3612:5,
3612:9, 3640:21
microporous [4] -
3448:3, 3574:6,
3574:8, 3591:2
microscope [6] -
3387:22, 3388:1,
3456:17, 3460:20,
3489:17, 3495:11
microscopes [4] -
3565:19, 3565:23,
3568:19, 3579:20
microscopical [1] -
3387:23
mid [2] - 3510:8,
3510:14
middle [10] -
3445:24, 3446:4,
3483:19, 3483:24,
3542:5, 3568:1,
3588:10, 3618:19,
3636:22, 3637:7
might [5] - 3414:16,
3417:7, 3480:2,
3572:6, 3593:15
migrates [2] -
3634:19, 3634:20
Milani [1] - 3626:19
miles [1] - 3380:3
milligrams [1] -
3483:14
millimeter [54] -
3421:15, 3424:12,

3424:20, 3425:3,
3426:18, 3447:10,
3447:17, 3452:20,
3459:2, 3459:12,
3459:24, 3460:1,
3460:8, 3460:21,
3462:20, 3464:6,
3464:9, 3464:11,
3468:9, 3468:13,
3469:1, 3469:22,
3472:4, 3472:22,
3472:24, 3473:9,
3473:21, 3475:23,
3477:11, 3481:11,
3481:18, 3481:22,
3556:22, 3556:24,
3557:4, 3557:7,
3557:19, 3557:22,
3573:14, 3576:8,
3576:9, 3580:22,
3580:25, 3588:6,
3588:24, 3591:19,
3591:24, 3602:10,
3602:15, 3603:19,
3608:7, 3623:4,
3623:16, 3636:24
millimeters [11] -
3448:10, 3464:1,
3481:13, 3573:13,
3576:16, 3580:23,
3613:13, 3619:19,
3619:20, 3640:25,
3641:5
million [13] -
3523:12, 3523:15,
3523:18, 3523:23,
3523:24, 3524:4,
3524:6, 3524:18,
3524:19, 3524:23,
3524:24
millions [4] -
3524:14, 3524:16,
3525:3, 3628:9
mind [2] - 3548:10,
3603:23
minimal [4] -
3455:23, 3477:6,
3477:12, 3507:6
Minimally [2] -
3564:7, 3564:11
Ministry [1] - 3402:4
minor [1] - 3566:7
minus [2] - 3510:8,
3510:9
minute [3] - 3408:19,
3498:12, 3632:17
minutes [11] -
3440:8, 3461:1,
3473:5, 3486:13,
3522:21, 3529:14,

3538:18, 3628:7,
3629:11, 3635:18
misleading [1] -
3576:20
mispronounce [1] -
3385:11
Mississippi [1] -
3376:21
mistake [1] -
3460:19
MITCHELL [3] -
3375:23, 3643:4,
3643:15
mix [3] - 3470:4,
3525:8, 3531:18
mixed [2] - 3389:6,
3531:17
mobility [1] - 3475:7
moderate [2] -
3518:6, 3568:25
modification [1] -
3613:5
modifications [6] -
3393:7, 3550:12,
3571:18, 3617:9,
3623:10, 3623:15
modified [6] -
3421:2, 3509:23,
3510:23, 3571:20,
3596:17, 3612:17
Modified [1] -
3595:21
molecular [1] -
3549:7
molecules [1] -
3549:9
moment [5] - 3382:6,
3425:12, 3443:6,
3448:3, 3476:10
money [5] - 3388:25,
3401:22, 3401:24,
3402:3, 3494:16
Monocryl [1] -
3613:7
monofilament [10] -
3505:5, 3505:12,
3505:17, 3553:4,
3553:5, 3553:12,
3553:13, 3553:15,
3576:12, 3578:20
monofilaments [2] -
3579:11, 3581:20
month [2] - 3517:9,
3517:20
months [12] -
3386:7, 3450:6,
3484:14, 3517:10,
3517:21, 3536:23,
3536:25, 3537:2,
3537:3, 3613:4,

3621:20
Montzen [1] - 3380:1
morbidity [2] -
3527:19, 3570:3
moreover [1] -
3550:7
morning [8] -
3379:22, 3379:23,
3472:23, 3493:10,
3498:23, 3533:10,
3540:6, 3550:24
morphological [2] -
3568:6, 3578:20
Morristown [1] -
3377:5
mortality [1] -
3634:22
most [25] - 3381:3,
3388:12, 3401:14,
3415:18, 3421:9,
3436:12, 3459:16,
3483:14, 3493:17,
3507:17, 3521:6,
3521:18, 3521:21,
3521:24, 3523:7,
3523:9, 3544:10,
3552:23, 3604:5,
3613:23, 3620:23,
3621:21, 3622:1,
3622:5, 3622:10
mostly [1] - 3493:21
motion [5] - 3409:3,
3409:9, 3414:11,
3417:16, 3418:1
mound [1] - 3599:15
mounds [2] -
3528:10, 3528:11
move [5] - 3408:6,
3508:10, 3567:3,
3571:25, 3587:24
moving [1] - 3633:10
MR [189] - 3379:8,
3379:21, 3386:17,
3386:23, 3386:24,
3394:13, 3394:16,
3394:21, 3405:3,
3405:8, 3405:12,
3405:16, 3407:14,
3407:20, 3407:21,
3407:24, 3408:11,
3409:6, 3409:11,
3409:17, 3410:16,
3410:21, 3411:19,
3412:20, 3414:16,
3415:9, 3415:11,
3415:12, 3415:14,
3415:20, 3416:3,
3416:18, 3417:11,
3417:15, 3418:16,
3418:20, 3419:7,

3419:21, 3419:25,
3420:6, 3420:7,
3422:25, 3427:3,
3427:4, 3427:5,
3430:13, 3430:14,
3430:15, 3430:18,
3431:11, 3432:14,
3437:23, 3437:24,
3438:1, 3438:4,
3438:5, 3438:7,
3438:11, 3438:12,
3449:22, 3449:23,
3450:2, 3450:5,
3450:10, 3450:25,
3451:9, 3451:13,
3451:17, 3452:7,
3452:9, 3452:13,
3452:15, 3452:16,
3464:20, 3464:24,
3471:8, 3471:13,
3477:23, 3477:25,
3483:20, 3483:22,
3483:23, 3485:23,
3486:2, 3486:7,
3486:13, 3486:16,
3486:20, 3487:16,
3487:17, 3489:2,
3489:5, 3489:11,
3492:4, 3492:20,
3492:24, 3508:3,
3518:23, 3519:2,
3519:7, 3519:10,
3519:12, 3527:20,
3527:25, 3529:13,
3530:10, 3530:14,
3537:15, 3537:19,
3538:2, 3538:5,
3538:9, 3538:10,
3539:6, 3539:10,
3554:6, 3554:9,
3554:24, 3554:25,
3597:6, 3597:10,
3600:3, 3600:6,
3600:10, 3600:15,
3600:19, 3601:7,
3601:14, 3602:11,
3602:12, 3602:13,
3603:5, 3603:8,
3603:12, 3603:13,
3603:23, 3603:25,
3604:1, 3604:2,
3607:18, 3607:20,
3609:7, 3609:11,
3618:14, 3618:17,
3620:10, 3620:15,
3625:7, 3625:10,
3626:12, 3626:14,
3626:18, 3627:6,
3627:10, 3628:1,
3628:2, 3628:5,
3628:21, 3629:1,

3629:13, 3629:15,
3629:18, 3630:25,
3631:5, 3631:7,
3631:11, 3631:15,
3631:16, 3632:23,
3633:9, 3633:11,
3635:7, 3635:9,
3635:13, 3635:14,
3635:20, 3635:22,
3635:25, 3636:4,
3638:5, 3638:8,
3640:1, 3640:8,
3640:9, 3640:13,
3640:17, 3641:14,
3641:16, 3641:22
MS [4] - 3409:7,
3410:1, 3412:12,
3418:5
Muhl [22] - 3460:24,
3464:13, 3472:9,
3472:11, 3473:15,
3473:16, 3476:4,
3476:13, 3477:21,
3478:17, 3479:15,
3482:12, 3486:9,
3489:14, 3555:5,
3555:13, 3556:3,
3559:20, 3586:1,
3586:11, 3599:3,
3609:16
Muhl's [6] - 3454:6,
3461:23, 3472:5,
3474:9, 3555:6,
3615:14
multiaxial [2] -
3476:18, 3552:3
multifilament [3] -
3553:6, 3553:15,
3553:16
multiple [2] -
3406:13, 3607:3
Munich [1] - 3400:1
Murphy [2] - 3416:7,
3416:14
muscular [1] -
3514:1
must [1] - 3420:20
naked [1] - 3613:6
name [12] - 3379:14,
3379:15, 3379:16,
3456:9, 3493:2,
3511:20, 3531:3,
3561:25, 3562:1,
3569:17, 3597:25,
3637:3
named [3] - 3425:20,
3553:10, 3618:12
naming [1] - 3553:13
narrow [1] - 3412:23
native [4] - 3496:6,

3594:5, 3595:17,
3614:5
near [2] - 3570:24,
3581:12
necessary [11] -
3382:19, 3387:1,
3388:8, 3458:18,
3460:14, 3470:8,
3489:7, 3594:4,
3595:16, 3602:24,
3618:9
necessity [1] -
3459:12
neck [1] - 3518:7
need [27] - 3387:22,
3387:25, 3392:24,
3401:22, 3404:17,
3408:5, 3415:18,
3455:3, 3459:14,
3463:16, 3474:23,
3481:17, 3481:21,
3482:15, 3483:4,
3489:17, 3508:12,
3519:6, 3521:17,
3526:6, 3530:9,
3571:5, 3597:22,
3605:7, 3605:9,
3614:14, 3640:22
needed [4] -
3421:11, 3424:19,
3560:4, 3608:5
needs [6] - 3433:12,
3435:25, 3437:20,
3449:7, 3453:9,
3453:11
negative [1] -
3403:13
neighborhood [2] -
3523:3, 3530:18
neighboring [4] -
3445:1, 3445:8,
3474:24, 3578:9
neovascularization
[2] - 3588:13, 3588:16
nerve [5] - 3551:7,
3551:11, 3632:10,
3632:11
nerves [2] - 3632:8,
3632:14
net [2] - 3617:1,
3617:5
Netherlands [2] -
3380:4, 3381:13
neuropathy [1] -
3551:6
neuropathy-related
[1] - 3551:6
never [35] - 3423:22,
3428:15, 3428:23,
3429:25, 3437:17,

3442:24, 3458:9,
3458:13, 3460:9,
3460:16, 3460:17,
3460:19, 3492:3,
3494:22, 3494:25,
3495:20, 3496:2,
3496:5, 3496:9,
3496:12, 3496:15,
3496:18, 3496:21,
3496:24, 3513:24,
3513:25, 3514:2,
3528:21, 3532:3,
3534:18, 3541:16,
3541:25, 3542:1,
3617:8, 3639:17
NEW [1] - 3375:1
new [13] - 3384:9,
3421:19, 3422:4,
3435:17, 3459:20,
3481:8, 3503:17,
3504:20, 3505:4,
3555:23, 3604:10,
3605:16, 3614:4
New [7] - 3375:10,
3376:5, 3376:15,
3377:5, 3427:23,
3643:6
newspaper [2] -
3562:21, 3562:24
newton [2] -
3474:21, 3474:25
next [48] - 3379:7,
3383:23, 3384:19,
3389:6, 3407:15,
3423:16, 3434:16,
3436:15, 3438:21,
3440:7, 3443:12,
3443:15, 3444:6,
3449:2, 3449:17,
3450:14, 3453:8,
3454:3, 3464:15,
3469:9, 3474:8,
3475:1, 3477:22,
3478:15, 3479:11,
3479:24, 3480:6,
3482:6, 3484:8,
3485:18, 3501:25,
3502:14, 3502:24,
3504:3, 3514:25,
3543:16, 3550:17,
3550:19, 3552:17,
3570:22, 3570:23,
3575:14, 3576:25,
3578:12, 3604:23,
3609:4, 3623:13
nice [2] - 3386:4,
3415:6
NIH [1] - 3401:18
nine [3] - 3466:3,
3593:21, 3594:22

NJ [1] - 3643:16
NO [1] - 3375:2
nonabsorbable [1] -
3581:19
none [5] - 3405:2,
3467:6, 3468:11,
3474:6, 3556:21
nonetheless [1] -
3534:4
nonimmunogenic
[2] - 3547:7, 3549:2
Norderstedt [14] -
3393:10, 3393:14,
3394:1, 3400:18,
3420:25, 3429:17,
3429:18, 3430:7,
3430:9, 3449:4,
3449:19, 3460:4,
3480:12, 3629:11
normal [1] - 3446:17
normally [1] -
3430:20
North [1] - 3499:8
nothing [4] -
3453:18, 3477:8,
3597:6, 3640:13
notifications [1] -
3413:15
notions [1] - 3547:15
nowhere [1] -
3478:25
nucleus [1] - 3566:4
Number [1] - 3643:5
number [33] -
3381:24, 3382:25,
3390:17, 3397:22,
3401:15, 3410:3,
3412:16, 3454:7,
3463:2, 3466:6,
3466:8, 3472:11,
3481:5, 3484:17,
3524:1, 3535:21,
3536:1, 3543:17,
3545:13, 3552:13,
3555:3, 3557:18,
3564:5, 3564:6,
3565:12, 3575:15,
3577:1, 3586:8,
3589:20, 3589:21,
3594:16, 3607:12,
3627:22
numbers [7] -
3475:14, 3594:25,
3620:9, 3626:21,
3626:23, 3637:9
numerous [4] -
3406:15, 3460:11,
3507:16, 3626:10
Numerous [1] -
3627:12

nylon [3] - 3502:1,
3502:4
O'MARA [1] -
3376:18
oberartz [2] -
3381:20, 3382:14
object [13] - 3412:20,
3416:25, 3417:2,
3418:8, 3419:23,
3430:18, 3431:3,
3431:10, 3450:9,
3527:25, 3558:12,
3604:17, 3630:25
objectify [1] -
3586:24
objection [46] -
3407:18, 3407:23,
3410:17, 3427:3,
3430:13, 3432:9,
3437:23, 3449:22,
3450:1, 3452:10,
3452:11, 3464:20,
3464:22, 3471:8,
3471:10, 3477:23,
3483:20, 3485:23,
3487:16, 3489:2,
3489:3, 3527:20,
3537:15, 3600:16,
3601:8, 3601:9,
3602:11, 3603:5,
3603:8, 3603:9,
3609:7, 3609:9,
3620:10, 3620:12,
3625:7, 3626:12,
3628:1, 3628:3,
3628:21, 3628:24,
3629:13, 3632:23,
3635:7, 3635:12,
3641:14, 3641:17
objective [1] -
3555:24
Objectives [1] -
3512:6
observations [1] -
3568:6
observed [2] -
3484:20, 3623:14
obstetrician [1] -
3497:8
obstetrics [1] -
3552:14
Obstetrics [2] -
3583:2, 3593:6
obtain [1] - 3387:13
obvious [2] - 3432:4,
3503:20
obviously [16] -
3412:21, 3412:22,
3414:11, 3418:21,
3419:9, 3430:25,

3434:8, 3462:25,
3472:20, 3496:12,
3497:11, 3515:20,
3515:21, 3522:23,
3529:18, 3614:18
occasions [1] -
3403:2
occur [8] - 3439:23,
3443:20, 3471:7,
3476:12, 3485:10,
3487:9, 3488:18,
3604:10
occurred [8] -
3411:9, 3430:17,
3450:4, 3486:1,
3527:24, 3537:18,
3600:5, 3626:17
occurrence [1] -
3550:3
occurs [3] - 3477:17,
3550:11, 3623:10
OF [2] - 3375:1,
3375:3
offer [5] - 3386:16,
3405:4, 3428:2,
3612:13, 3612:17
offered [1] - 3612:18
offers [1] - 3586:23
office [1] - 3381:18
OFFICES [1] -
3376:9
official [1] - 3381:17
often [7] - 3389:10,
3523:9, 3537:24,
3579:1, 3613:23,
3622:7, 3630:18
Ohio [1] - 3376:11
older [3] - 3421:9,
3458:24, 3523:14
oligofilament [1] -
3553:16
once [11] - 3396:23,
3445:18, 3452:25,
3501:9, 3501:16,
3546:5, 3548:18,
3565:8, 3571:7,
3602:9, 3613:7
oncologic [1] -
3390:14
one [142] - 3381:3,
3381:4, 3381:11,
3390:3, 3391:9,
3395:11, 3408:8,
3409:7, 3412:23,
3417:13, 3421:25,
3422:21, 3425:7,
3425:11, 3432:20,
3435:1, 3436:23,
3436:25, 3443:8,
3444:20, 3446:20,

3447:6, 3450:14,
3452:1, 3454:17,
3454:18, 3457:23,
3458:12, 3458:13,
3463:10, 3463:17,
3464:3, 3464:4,
3466:1, 3467:1,
3470:2, 3474:19,
3475:17, 3476:22,
3478:6, 3479:16,
3480:6, 3480:10,
3483:10, 3488:2,
3489:10, 3490:25,
3494:17, 3502:20,
3503:14, 3507:12,
3517:3, 3520:6,
3520:7, 3522:23,
3523:6, 3524:22,
3525:12, 3526:13,
3526:23, 3527:1,
3527:10, 3528:1,
3528:5, 3530:1,
3530:22, 3533:7,
3533:24, 3534:21,
3536:3, 3536:7,
3536:16, 3539:4,
3540:13, 3541:11,
3542:10, 3543:2,
3546:9, 3551:17,
3556:2, 3556:5,
3559:6, 3567:15,
3567:16, 3567:18,
3567:22, 3569:6,
3569:9, 3569:23,
3572:5, 3572:10,
3577:4, 3578:11,
3578:12, 3578:14,
3579:25, 3583:18,
3584:22, 3589:11,
3589:20, 3589:21,
3593:14, 3593:20,
3594:10, 3594:11,
3594:22, 3595:4,
3598:13, 3598:18,
3599:22, 3602:5,
3602:6, 3604:17,
3607:24, 3608:2,
3610:12, 3611:8,
3613:2, 3617:11,
3618:19, 3620:16,
3621:5, 3621:12,
3627:20, 3628:10,
3628:16, 3629:9,
3631:17, 3632:16,
3634:14, 3636:6,
3637:4, 3637:23
One [1] - 3377:4
one-and-a-third [1] -
3494:17
ones [7] - 3420:17,
3487:4, 3530:23,

3541:11, 3591:12,
3620:19, 3637:4
ongoing [1] -
3423:20
onset [1] - 3551:16
open [11] - 3414:7,
3466:7, 3467:20,
3469:14, 3472:6,
3477:10, 3506:7,
3526:16, 3532:7,
3553:21, 3596:14
opened [1] - 3601:2
operating [1] -
3506:15
operation [4] -
3386:2, 3511:2,
3533:1, 3551:11
operations [8] -
3381:16, 3382:21,
3382:25, 3390:10,
3390:18, 3390:19,
3422:1, 3500:11
Ophelie [1] - 3435:13
opinion [32] -
3424:23, 3425:3,
3428:10, 3428:13,
3428:14, 3428:20,
3428:22, 3429:11,
3461:22, 3461:25,
3465:1, 3467:11,
3468:25, 3477:9,
3483:1, 3484:20,
3485:9, 3488:15,
3488:22, 3489:12,
3490:13, 3490:18,
3491:10, 3491:16,
3491:21, 3491:23,
3492:2, 3544:9,
3549:25, 3624:12,
3624:16, 3633:8
opinions [13] -
3403:7, 3405:10,
3427:21, 3427:22,
3428:2, 3436:6,
3449:8, 3453:13,
3464:19, 3484:24,
3501:1, 3501:5,
3623:2
opportunity [6] -
3391:14, 3408:4,
3462:10, 3462:12,
3478:2, 3529:10
opposed [2] -
3386:20, 3603:11
Optilene [10] -
3556:11, 3556:18,
3563:12, 3563:22,
3565:2, 3566:14,
3566:19, 3568:20,
3621:15, 3638:24

optimal [1] - 3484:20
optimum [2] -
3404:9, 3481:14
option [4] - 3522:10,
3526:13, 3526:20,
3615:4
OR [2] - 3386:11,
3388:10
oral [1] - 3399:2
order [18] - 3385:10,
3385:12, 3387:12,
3401:7, 3424:18,
3426:23, 3434:11,
3434:12, 3457:4,
3457:5, 3459:5,
3459:13, 3465:1,
3506:8, 3608:3,
3634:6
organ [12] - 3496:3,
3496:10, 3526:3,
3526:6, 3526:9,
3528:25, 3535:9,
3583:12, 3585:8,
3595:6, 3625:20,
3628:17
organize [1] - 3389:3
organs [7] - 3429:9,
3526:17, 3630:7,
3631:23, 3632:8,
3632:20, 3634:7
orient [1] - 3463:16
original [2] -
3487:24, 3540:19
otherwise [4] -
3428:4, 3473:22,
3625:17, 3635:18
ourselves [1] -
3432:15
outcome [6] -
3442:15, 3448:9,
3456:7, 3597:18,
3598:2, 3599:19
outcomes [3] -
3570:4, 3626:11,
3627:12
outline [1] - 3394:19
outlined [1] -
3586:18
outside [5] -
3392:12, 3392:16,
3417:1, 3439:4,
3444:25
outstanding [2] -
3424:6, 3427:19
outweighed [1] -
3534:6
Overall [2] - 3568:23,
3568:24
overlap [3] -
3419:11, 3594:21,

3633:25
overruled [7] -
3432:10, 3464:23,
3471:10, 3489:3,
3609:9, 3628:24,
3635:12
oversized [1] -
3421:10
Owens [1] - 3415:10
own [3] - 3389:19,
3529:14, 3584:18
oxygen [1] - 3383:14
P.J. [1] - 3375:16
p.m. [5] - 3492:11,
3492:12, 3554:15,
3554:16, 3642:8
P0753 [1] - 3452:7
page [37] - 3501:13,
3501:25, 3502:15,
3502:24, 3503:3,
3503:4, 3504:3,
3510:21, 3511:5,
3513:1, 3513:2,
3514:25, 3533:7,
3535:14, 3541:17,
3543:16, 3545:12,
3549:12, 3550:17,
3552:18, 3556:6,
3556:7, 3563:14,
3565:25, 3570:22,
3570:23, 3570:24,
3572:16, 3575:14,
3576:25, 3579:24,
3580:7, 3587:11,
3588:10, 3594:1,
3595:9, 3596:6
pages [5] - 3406:8,
3406:18, 3428:8,
3565:5, 3641:11
paid [8] - 3407:8,
3493:7, 3494:17,
3494:18, 3559:17,
3560:23, 3562:4,
3563:5
pain [20] - 3385:21,
3435:23, 3437:20,
3444:15, 3471:5,
3518:2, 3532:21,
3550:20, 3550:23,
3551:1, 3551:8,
3551:12, 3551:15,
3551:16, 3564:22,
3570:2, 3570:15,
3638:19, 3639:8
paper [5] - 3519:20,
3520:2, 3576:23,
3602:14, 3603:24
papers [1] - 3503:19
paragraph [13] -
3499:22, 3504:4,

3504:18, 3506:4,
3510:22, 3547:6,
3566:13, 3568:23,
3570:11, 3587:5,
3596:7, 3601:5
paragraphs [2] -
3507:11, 3601:4
parallel [3] - 3383:9,
3512:16, 3604:8
parastomal [1] -
3528:17
Parietex [1] -
3570:17
Parkway [2] -
3376:4, 3376:20
part [23] - 3380:2,
3382:19, 3387:15,
3388:10, 3388:17,
3391:9, 3396:18,
3410:6, 3410:9,
3414:11, 3418:3,
3430:9, 3430:25,
3451:10, 3476:17,
3490:2, 3513:10,
3581:5, 3598:16,
3607:25, 3609:22,
3628:10, 3628:11
partial [1] - 3602:18
partially [1] -
3531:16
participant [1] -
3440:1
participants [4] -
3449:21, 3449:25,
3451:20, 3451:23
particular [4] -
3450:7, 3501:13,
3526:9, 3581:16
particularly [1] -
3518:8
parts [1] - 3546:6
Parviz [1] - 3457:10
pass [5] - 3381:17,
3389:21, 3390:18,
3407:16, 3408:4
passed [3] -
3381:15, 3381:17,
3407:17
passing [2] - 3381:8,
3408:9
past [2] - 3406:23,
3507:14
paste [1] - 3453:18
patent [5] - 3561:14,
3561:16, 3561:19,
3561:22, 3561:23
patents [7] -
3402:18, 3402:20,
3561:1, 3561:4,
3561:6, 3561:8,

3561:9
pathologist [3] -
3395:17, 3593:15
pathologists [1] -
3593:18
pathology [6] -
3380:18, 3388:5,
3388:6, 3388:9,
3395:10, 3396:11
patient [18] -
3409:16, 3418:25,
3426:23, 3427:13,
3448:7, 3448:19,
3479:9, 3485:16,
3507:6, 3510:25,
3533:17, 3534:8,
3546:24, 3547:2,
3551:11, 3570:3,
3614:9, 3619:13
patient-centric [1] -
3614:9
patients [48] -
3381:13, 3381:24,
3383:22, 3385:19,
3385:24, 3386:3,
3397:9, 3425:2,
3484:21, 3507:15,
3509:22, 3510:7,
3510:17, 3517:8,
3517:19, 3518:2,
3518:6, 3522:11,
3522:13, 3523:3,
3530:18, 3530:24,
3531:5, 3531:14,
3531:23, 3534:3,
3536:1, 3583:16,
3583:17, 3583:25,
3584:1, 3585:7,
3591:12, 3597:18,
3610:3, 3622:4,
3625:13, 3625:20,
3625:24, 3625:25,
3626:1, 3627:22,
3634:18, 3634:24,
3638:12, 3640:22
pause [1] - 3551:9
pay [2] - 3405:20,
3406:20
paying [1] - 3562:6
Peak [2] - 3604:24,
3606:11
peer [8] - 3397:14,
3397:16, 3397:20,
3400:22, 3401:1,
3460:2, 3535:22,
3600:17
peer-reviewed [5] -
3397:14, 3397:16,
3397:20, 3460:2,
3535:22

peers [1] - 3400:5
peers' [1] - 3401:2
pelvic [76] - 3397:25,
3400:5, 3400:10,
3400:19, 3403:11,
3403:14, 3404:22,
3428:12, 3428:17,
3428:24, 3429:8,
3429:10, 3429:23,
3431:13, 3431:22,
3432:19, 3433:5,
3433:14, 3433:21,
3434:12, 3442:9,
3443:4, 3443:10,
3468:17, 3476:20,
3490:16, 3495:24,
3496:3, 3496:9,
3496:15, 3497:3,
3497:5, 3497:15,
3517:9, 3517:13,
3517:20, 3517:23,
3521:25, 3522:6,
3522:11, 3522:14,
3528:25, 3535:9,
3535:23, 3558:19,
3582:4, 3583:12,
3583:18, 3584:22,
3585:8, 3592:20,
3593:8, 3593:11,
3594:2, 3595:6,
3613:11, 3614:3,
3615:1, 3621:19,
3625:19, 3628:20,
3629:20, 3630:5,
3630:7, 3630:11,
3630:25, 3631:6,
3631:9, 3631:23,
3632:20, 3632:24,
3633:2, 3633:4,
3636:14, 3639:19
pelvis [6] - 3437:14,
3441:11, 3442:25,
3462:1, 3520:6,
3620:21
pending [1] -
3609:12
people [16] -
3393:13, 3411:11,
3416:21, 3419:17,
3420:25, 3437:18,
3439:7, 3467:23,
3502:6, 3523:23,
3524:11, 3525:4,
3530:2, 3543:10,
3618:6, 3628:9
people's [1] -
3519:25
per [5] - 3401:1,
3401:4, 3401:6,
3474:21, 3524:9

percent [40] -
3391:11, 3399:8,
3399:9, 3421:12,
3422:17, 3422:19,
3422:20, 3422:23,
3453:2, 3461:6,
3461:7, 3461:20,
3461:24, 3469:14,
3470:14, 3470:15,
3470:17, 3472:6,
3475:6, 3475:9,
3476:1, 3476:2,
3505:1, 3522:2,
3540:18, 3556:19,
3557:22, 3558:1,
3558:3, 3558:7,
3567:7, 3586:5,
3586:6, 3586:7,
3591:23, 3617:10,
3638:24, 3639:7,
3639:15
percentage [9] -
3399:4, 3461:4,
3461:17, 3463:11,
3464:2, 3466:7,
3467:19, 3470:12,
3525:5
perfect [4] - 3508:16,
3534:16, 3534:18,
3615:4
perfectly [1] - 3587:8
perform [5] -
3382:17, 3382:20,
3390:13, 3403:14,
3464:5
performed [13] -
3385:9, 3467:7,
3495:20, 3496:2,
3496:5, 3496:9,
3506:23, 3506:24,
3507:5, 3510:25,
3523:7, 3523:10,
3624:22
performing [1] -
3530:16
perhaps [1] - 3526:3
perifilament [2] -
3606:22, 3607:8
Perigee [1] - 3484:22
period [8] - 3382:22,
3383:1, 3387:12,
3414:10, 3418:13,
3493:22, 3497:20,
3497:24
permanent [5] -
3445:4, 3459:14,
3534:11, 3534:14,
3622:23
permanently [10] -
3393:24, 3396:6,

3402:16, 3428:12,
3428:24, 3434:12,
3462:1, 3477:13,
3488:19, 3491:18
permission [2] -
3384:1, 3384:3
permit [3] - 3588:4,
3588:11, 3609:17
PERRETTI [1] -
3377:3
persist [1] - 3423:25
persists [1] - 3445:3
person [6] - 3404:15,
3415:6, 3415:7,
3465:10, 3525:15,
3526:7
personal [2] -
3401:23, 3431:6
personally [2] -
3530:4, 3582:16
persuasive [1] -
3416:22
ph [1] - 3375:24
phase [1] - 3450:19
phenomenon [4] -
3444:14, 3549:25,
3622:10, 3623:14
phone [1] - 3393:20
photo [1] - 3454:4
photographs [1] -
3456:11
phrase [3] - 3498:19,
3590:2, 3590:3
physician [1] -
3504:23
physicians [4] -
3500:10, 3502:5,
3564:6, 3594:16
physiological [5] -
3421:2, 3421:7,
3446:17, 3588:4,
3614:15
physiology [2] -
3420:20, 3433:13
pick [1] - 3595:10
picture [6] - 3483:19,
3541:23, 3546:3,
3562:17, 3562:20,
3637:6
pictures [2] - 3577:1,
3606:23
piece [5] - 3456:16,
3526:3, 3584:18,
3585:2, 3616:16
pieces [1] - 3406:10
Piet [1] - 3409:9
pig [5] - 3621:20,
3638:3, 3638:5,
3638:7, 3638:9
pigs [6] - 3564:25,

3565:9, 3565:11,
3565:16, 3568:13,
3568:20
pinch [1] - 3584:18
pioneering [1] -
3503:14
pixels [3] - 3463:2,
3467:17
place [27] - 3380:6,
3433:13, 3435:10,
3442:9, 3461:18,
3469:6, 3475:15,
3476:8, 3485:13,
3487:25, 3488:10,
3489:25, 3490:25,
3514:9, 3532:6,
3543:20, 3548:6,
3597:25, 3614:16,
3623:25, 3625:4,
3629:5, 3630:22,
3632:13, 3633:14,
3633:25, 3634:16
PLACE [1] - 3375:9
placed [22] - 3427:2,
3429:3, 3455:23,
3461:9, 3461:22,
3470:13, 3475:5,
3476:5, 3478:4,
3481:2, 3485:3,
3488:14, 3496:18,
3496:21, 3496:24,
3562:24, 3568:3,
3615:20, 3617:19,
3629:4, 3630:17,
3632:4
places [3] - 3471:15,
3479:3, 3514:12
placing [2] -
3386:13, 3613:10
Plaintiff's [3] -
3600:1, 3612:22,
3613:1
plaintiffs [4] -
3379:8, 3405:3,
3412:19, 3519:4
Plaintiffs [4] -
3375:3, 3376:7,
3376:12, 3376:17
Plaintiffs' [1] -
3540:3
plane [5] - 3461:10,
3461:19, 3488:4
planet [1] - 3525:4
planned [1] - 3433:4
plastic [2] - 3503:18,
3503:20
plate [13] - 3386:8,
3425:1, 3429:8,
3448:6, 3448:14,
3470:20, 3470:21,

3471:2, 3479:5,
3544:4, 3607:4,
3617:1, 3617:6
plates [3] - 3457:4,
3471:22, 3619:9
play [3] - 3461:12,
3485:22, 3620:14
Plaza [1] - 3377:4
pleasure [2] -
3493:4, 3493:6
plenty [1] - 3529:8
PLLC [1] - 3376:18
PLT0261 [1] - 3540:4
PLT0268 [1] -
3420:19
PLT0346 [2] -
3555:4, 3567:2
PLT0689 [1] - 3600:2
plus [1] - 3538:11
point [27] - 3386:21,
3389:5, 3411:20,
3411:24, 3412:8,
3413:18, 3418:22,
3423:1, 3423:16,
3433:18, 3436:10,
3441:19, 3442:25,
3474:19, 3474:24,
3475:1, 3483:5,
3485:2, 3504:14,
3538:2, 3539:12,
3587:12, 3614:1,
3625:11, 3633:10,
3641:7
pointed [3] - 3610:9,
3631:19, 3641:3
points [2] - 3586:11,
3632:16
polyester [2] -
3502:23, 3570:1
polyethylene [4] -
3503:17, 3503:25,
3504:9, 3504:20
polyglactin [1] -
3531:19
polymer [3] -
3441:18, 3441:20,
3610:14
polypropylene [102]
- 3388:15, 3422:6,
3423:8, 3426:5,
3440:23, 3441:9,
3441:13, 3441:17,
3442:9, 3442:12,
3442:13, 3442:17,
3442:18, 3442:24,
3443:4, 3443:9,
3447:9, 3456:15,
3457:23, 3461:14,
3487:14, 3487:24,
3498:13, 3498:14,

3500:4, 3500:9,
3504:1, 3504:13,
3505:4, 3505:12,
3505:16, 3505:23,
3507:13, 3512:21,
3513:4, 3513:5,
3513:14, 3513:21,
3513:25, 3514:11,
3517:5, 3519:14,
3520:11, 3521:5,
3521:6, 3521:18,
3521:21, 3521:24,
3522:3, 3522:6,
3522:8, 3523:2,
3523:21, 3523:25,
3524:7, 3524:8,
3525:6, 3525:13,
3531:1, 3531:6,
3531:10, 3531:20,
3532:5, 3532:8,
3540:10, 3540:18,
3558:6, 3563:11,
3563:22, 3565:2,
3570:14, 3575:20,
3575:24, 3576:2,
3576:13, 3578:21,
3579:7, 3579:12,
3581:19, 3582:4,
3583:7, 3583:11,
3583:19, 3584:2,
3588:7, 3610:7,
3610:8, 3610:24,
3611:1, 3612:1,
3618:11, 3621:2,
3628:9, 3628:11,
3628:15, 3633:20,
3634:11, 3636:16,
3638:18
Polypropylene [6] -
3499:22, 3503:11,
3507:12, 3552:22,
3575:10, 3578:5
polyvinyl [3] -
3501:9, 3501:12,
3501:15
Polyvinyl [1] -
3501:23
polyvinylidene [1] -
3610:17
poor [1] - 3518:11
pop [1] - 3487:20
popular [1] - 3507:17
Pore [7] - 3469:12,
3572:21, 3588:10,
3595:11, 3595:12,
3603:15, 3609:17
pore [132] - 3421:13,
3424:6, 3424:8,
3424:20, 3424:24,
3425:17, 3425:21,

3426:17, 3427:18,
3433:8, 3442:8,
3447:1, 3447:10,
3448:1, 3448:2,
3448:5, 3448:8,
3452:19, 3453:22,
3453:23, 3453:25,
3455:10, 3457:3,
3457:12, 3457:13,
3458:3, 3458:7,
3458:11, 3458:12,
3458:13, 3458:24,
3459:1, 3459:4,
3459:6, 3459:16,
3459:24, 3460:1,
3460:10, 3461:8,
3461:11, 3462:13,
3462:20, 3462:21,
3463:6, 3463:18,
3464:4, 3464:6,
3464:16, 3464:18,
3464:25, 3465:16,
3466:11, 3466:14,
3466:17, 3467:13,
3467:17, 3467:24,
3469:1, 3469:16,
3469:17, 3469:22,
3470:2, 3470:9,
3471:1, 3471:21,
3472:22, 3472:24,
3481:1, 3481:10,
3481:13, 3481:15,
3481:18, 3481:21,
3485:5, 3485:7,
3550:13, 3553:2,
3553:7, 3557:18,
3557:21, 3565:1,
3574:9, 3575:11,
3576:5, 3576:8,
3576:15, 3580:21,
3580:25, 3588:3,
3588:12, 3590:23,
3590:24, 3591:19,
3592:2, 3594:2,
3595:14, 3597:2,
3598:7, 3598:8,
3599:16, 3599:17,
3599:20, 3602:5,
3602:6, 3604:4,
3604:20, 3604:24,
3605:2, 3605:9,
3605:10, 3606:11,
3608:21, 3608:24,
3609:2, 3609:5,
3613:22, 3616:2,
3617:10, 3617:24,
3618:12, 3618:20,
3619:20, 3619:23,
3619:25, 3623:5,
3623:7, 3623:12,
3623:15

pores [117] -
3421:15, 3422:4,
3422:8, 3422:11,
3424:12, 3425:2,
3429:1, 3429:2,
3429:3, 3444:1,
3447:8, 3453:6,
3454:16, 3455:1,
3455:7, 3455:9,
3455:17, 3455:18,
3455:21, 3455:24,
3456:20, 3456:22,
3457:16, 3457:17,
3457:19, 3458:1,
3458:15, 3458:16,
3458:19, 3459:12,
3460:11, 3460:14,
3461:13, 3461:16,
3463:11, 3463:14,
3463:23, 3464:2,
3465:7, 3465:10,
3466:22, 3467:3,
3468:9, 3468:13,
3468:18, 3469:23,
3469:25, 3470:4,
3470:5, 3470:7,
3470:12, 3470:15,
3472:3, 3472:6,
3472:8, 3473:2,
3473:4, 3473:8,
3473:18, 3474:1,
3474:5, 3475:22,
3475:25, 3476:2,
3476:7, 3476:10,
3477:5, 3477:10,
3477:12, 3477:18,
3478:13, 3478:20,
3479:4, 3482:15,
3482:17, 3483:5,
3489:19, 3516:4,
3516:5, 3516:22,
3533:15, 3538:6,
3538:23, 3539:3,
3539:17, 3539:19,
3539:25, 3540:1,
3544:5, 3544:6,
3556:22, 3574:23,
3575:23, 3591:1,
3591:14, 3592:1,
3592:8, 3596:22,
3599:7, 3599:11,
3602:17, 3605:11,
3605:19, 3606:20,
3606:21, 3607:7,
3607:8, 3607:15,
3611:4, 3613:8,
3613:12, 3613:14,
3616:11, 3617:14,
3618:4, 3619:2
Porosity [1] -
3587:25

<p>porosity [39] - 3465:25, 3466:2, 3466:3, 3466:5, 3466:8, 3466:25, 3468:6, 3472:3, 3472:7, 3477:10, 3478:23, 3480:2, 3482:8, 3516:10, 3516:11, 3555:2, 3556:19, 3557:23, 3558:1, 3558:4, 3558:14, 3559:1, 3559:8, 3563:16, 3567:8, 3586:4, 3586:24, 3587:6, 3587:20, 3588:21, 3596:17, 3596:22, 3597:4, 3599:7, 3620:4, 3638:25, 3639:7, 3639:16</p> <p>porous [5] - 3544:24, 3571:22, 3576:8, 3576:15, 3608:3</p> <p>portion [2] - 3407:15, 3523:20</p> <p>portions [1] - 3555:14</p> <p>pose [1] - 3508:11</p> <p>position [4] - 3413:1, 3538:15, 3568:4, 3575:11</p> <p>possibility [1] - 3466:24</p> <p>possible [12] - 3427:9, 3435:8, 3476:18, 3488:8, 3502:5, 3530:5, 3571:20, 3581:17, 3582:15, 3598:1, 3612:9, 3616:18</p> <p>post [5] - 3411:16, 3411:18, 3413:20, 3450:8, 3450:23</p> <p>post-date [1] - 3413:20</p> <p>post-dating [1] - 3450:8</p> <p>post-surgical [1] - 3411:16</p> <p>posterior [1] - 3536:11</p> <p>postoperative [7] - 3517:8, 3517:20, 3517:24, 3518:2, 3570:15, 3638:19, 3639:8</p> <p>potential [2] - 3501:16, 3533:2</p> <p>potentially [1] - 3524:16</p>	<p>pounds [14] - 3476:5, 3476:7, 3478:6, 3478:8, 3478:10, 3478:11, 3478:12, 3478:17, 3489:20, 3489:21, 3615:20, 3616:1, 3617:16, 3618:2</p> <p>power [3] - 3487:23, 3626:3, 3640:23</p> <p>PowerPoint [4] - 3451:25, 3452:2, 3577:6, 3577:8</p> <p>PP [2] - 3422:17, 3576:14</p> <p>pre-2006 [1] - 3412:17</p> <p>precise [1] - 3463:12</p> <p>precisely [1] - 3458:6</p> <p>preclinical [3] - 3422:5, 3427:16, 3621:25</p> <p>precursor [1] - 3512:11</p> <p>precut [2] - 3634:2, 3634:5</p> <p>predate [1] - 3635:11</p> <p>predates [1] - 3635:9</p> <p>predict [2] - 3468:21, 3621:23</p> <p>predicting [1] - 3458:20</p> <p>predicts [2] - 3459:21, 3599:18</p> <p>preliminary [1] - 3601:25</p> <p>prepared [1] - 3643:7</p> <p>preparing [2] - 3407:6, 3407:7</p> <p>prescribe [1] - 3538:1</p> <p>present [6] - 3400:1, 3524:10, 3578:24, 3579:6, 3581:17, 3586:23</p> <p>presentation [4] - 3399:2, 3399:24, 3400:1, 3452:3</p> <p>presentations [2] - 3426:21, 3460:15</p> <p>presented [1] - 3452:1</p> <p>preservation [1] - 3587:19</p> <p>preserve [3] - 3477:24, 3485:3, 3546:10</p> <p>preserved [3] -</p>	<p>3432:10, 3452:11, 3464:22</p> <p>preserving [1] - 3597:3</p> <p>presumably [1] - 3414:12</p> <p>pretailored [1] - 3517:4</p> <p>pretty [3] - 3414:2, 3414:5, 3542:4</p> <p>prevent [6] - 3409:12, 3424:18, 3448:5, 3459:13, 3588:3, 3611:4</p> <p>previous [3] - 3474:20, 3518:9, 3535:17</p> <p>previously [1] - 3432:6</p> <p>primarily [1] - 3413:22</p> <p>primary [4] - 3417:16, 3417:18, 3418:1, 3570:2</p> <p>principal [5] - 3388:19, 3391:16, 3391:21, 3392:8, 3480:11</p> <p>principle [3] - 3421:8, 3569:22, 3633:18</p> <p>principles [7] - 3381:15, 3395:21, 3396:3, 3431:20, 3433:6, 3433:9, 3434:6</p> <p>priority [1] - 3449:14</p> <p>privatdozent [2] - 3384:10, 3384:18</p> <p>probability [2] - 3427:25, 3428:4</p> <p>problem [17] - 3392:19, 3412:3, 3416:12, 3450:17, 3451:24, 3455:6, 3455:14, 3456:7, 3462:2, 3524:13, 3537:25, 3543:20, 3548:23, 3610:4, 3615:2, 3623:25, 3625:4</p> <p>problems [27] - 3385:23, 3397:8, 3399:6, 3400:20, 3424:19, 3426:17, 3429:13, 3435:7, 3436:11, 3437:3, 3437:6, 3437:12, 3437:15, 3438:14, 3438:19, 3439:5,</p>	<p>3439:23, 3447:23, 3449:5, 3449:10, 3450:13, 3471:5, 3471:23, 3487:9, 3507:16, 3533:17, 3622:9</p> <p>procedure [16] - 3435:21, 3464:13, 3465:25, 3466:9, 3466:10, 3467:15, 3472:25, 3497:6, 3506:16, 3510:25, 3523:8, 3523:10, 3562:2, 3586:17, 3586:18, 3627:13</p> <p>procedures [4] - 3390:14, 3468:20, 3506:17, 3506:23</p> <p>proceed [6] - 3405:11, 3420:1, 3452:14, 3471:12, 3492:19, 3519:5</p> <p>Proceedings [1] - 3643:9</p> <p>process [3] - 3445:23, 3606:21, 3607:8</p> <p>produce [4] - 3421:1, 3459:1, 3560:3, 3617:7</p> <p>produced [1] - 3553:24</p> <p>product [15] - 3407:21, 3410:8, 3440:19, 3450:15, 3462:5, 3469:2, 3469:15, 3482:18, 3488:19, 3491:12, 3491:15, 3502:11, 3531:25, 3577:19, 3613:6</p> <p>production [1] - 3465:18</p> <p>products [2] - 3386:13, 3533:20</p> <p>Prof [19] - 3435:18, 3435:20, 3440:9, 3443:15, 3447:19, 3448:23, 3464:13, 3473:16, 3476:4, 3477:21, 3482:12, 3574:16, 3590:8, 3590:11, 3590:15, 3603:2, 3615:13, 3638:14</p> <p>PROF [2] - 3378:5, 3379:11</p> <p>profession [2] - 3380:11, 3380:15</p> <p>professor [4] -</p>	<p>3384:17, 3384:18, 3384:25, 3385:5</p> <p>program [1] - 3473:23</p> <p>Project [9] - 3611:7, 3611:11, 3611:15, 3611:19, 3612:23, 3612:24, 3614:2, 3615:10</p> <p>project [7] - 3384:20, 3401:21, 3435:5, 3436:11, 3563:1, 3611:7, 3625:2</p> <p>projects [4] - 3388:23, 3388:24, 3481:8, 3560:22</p> <p>prolapse [16] - 3496:3, 3496:10, 3511:1, 3512:3, 3512:9, 3516:18, 3516:23, 3517:3, 3528:25, 3535:9, 3537:10, 3537:11, 3583:12, 3585:8, 3595:6, 3625:20</p> <p>Prolene [22] - 3466:20, 3469:13, 3512:8, 3512:11, 3512:12, 3512:15, 3514:15, 3514:16, 3514:19, 3515:1, 3515:5, 3515:10, 3515:12, 3515:18, 3516:2, 3516:4, 3516:21, 3529:6, 3531:8, 3577:16, 3591:10, 3591:11</p> <p>proliferation [1] - 3602:6</p> <p>Prolift [85] - 3380:22, 3387:19, 3388:16, 3391:24, 3395:1, 3400:5, 3402:15, 3404:5, 3407:21, 3408:3, 3421:17, 3422:11, 3428:11, 3428:23, 3429:12, 3429:22, 3430:1, 3434:7, 3434:9, 3435:2, 3435:5, 3436:25, 3437:5, 3438:14, 3439:10, 3440:17, 3441:10, 3441:14, 3453:24, 3454:8, 3462:14, 3463:18, 3467:12, 3468:22, 3469:11, 3470:25, 3471:6, 3471:21, 3474:12, 3481:25, 3482:3,</p>
---	--	---	---	--

3484:12, 3484:14,
3484:22, 3488:18,
3490:7, 3491:11,
3491:24, 3496:12,
3496:25, 3498:14,
3505:14, 3505:16,
3515:8, 3518:18,
3518:19, 3528:13,
3529:5, 3535:10,
3535:17, 3536:6,
3537:4, 3538:6,
3539:18, 3540:22,
3542:11, 3543:2,
3556:16, 3557:10,
3557:11, 3558:17,
3572:1, 3585:9,
3586:12, 3586:19,
3588:19, 3589:7,
3593:24, 3609:20,
3625:20, 3627:15,
3636:7, 3639:14,
3639:17
Prolift+M [8] -
3536:7, 3538:5,
3538:9, 3538:11,
3538:23, 3539:13,
3539:17, 3611:13
Prolift/Gynemesh
[1] - 3491:17
Prolifts [3] -
3536:10, 3585:13,
3636:10
promise [1] - 3594:8
promoter [1] -
3435:1
prompt [1] - 3507:7
proof [1] - 3451:3
proper [3] - 3426:6,
3459:6, 3490:16
properly [1] -
3464:10
properties [3] -
3393:4, 3564:17,
3614:4
property [1] -
3616:19
proposal [1] -
3459:20
proposed [4] -
3457:12, 3459:19,
3467:16, 3473:3
prospectively [1] -
3583:10
prostheses [7] -
3590:21, 3591:5,
3591:6, 3591:14,
3592:1, 3592:20,
3593:11
prosthesis [3] -
3504:21, 3505:6,

3552:23
prosthetic [1] -
3507:18
prosthetics [1] -
3499:18
Prosthetics [2] -
3499:7, 3499:17
protocol [1] -
3587:14
prove [1] - 3460:20
proven [1] - 3427:9
provide [2] - 3554:1,
3596:23
provided [2] -
3413:9, 3611:24
provides [1] - 3393:2
providing [3] -
3430:19, 3605:7,
3605:10
PS [55] - 3391:24,
3408:2, 3428:11,
3428:23, 3434:8,
3438:14, 3439:9,
3439:24, 3445:18,
3447:24, 3449:5,
3450:12, 3454:1,
3461:4, 3464:18,
3465:11, 3466:13,
3469:2, 3470:13,
3470:24, 3471:6,
3472:21, 3475:21,
3477:4, 3483:2,
3491:11, 3491:17,
3491:25, 3496:15,
3498:15, 3505:15,
3515:5, 3515:8,
3515:19, 3515:21,
3516:5, 3539:19,
3540:22, 3553:8,
3553:9, 3572:22,
3574:22, 3611:9,
3611:12, 3613:19,
3613:22, 3615:2,
3615:15, 3615:21,
3617:2, 3617:6,
3617:21, 3618:18,
3620:20, 3634:2
PTFE [3] - 3563:24,
3565:3, 3621:14
public [1] - 3413:15
publication [8] -
3421:22, 3421:24,
3425:18, 3457:10,
3511:21, 3523:17,
3590:2, 3607:23
publications [12] -
3384:5, 3385:9,
3396:2, 3396:3,
3397:19, 3397:22,
3398:2, 3401:6,

3459:10, 3460:18,
3491:4, 3535:22
publish [3] -
3384:21, 3423:15,
3555:20
published [26] -
3397:12, 3397:16,
3398:10, 3401:8,
3404:20, 3415:2,
3424:1, 3425:8,
3425:13, 3437:22,
3447:18, 3479:15,
3499:8, 3508:20,
3533:23, 3535:22,
3564:1, 3574:18,
3575:7, 3582:8,
3592:10, 3596:3,
3596:4, 3601:23,
3603:11, 3612:18
pull [2] - 3535:14,
3550:16
pulled [6] - 3490:8,
3584:25, 3616:1,
3639:2, 3639:3,
3639:11
pulling [1] - 3476:14
punch [3] - 3583:16,
3584:10, 3584:16
punitive [1] -
3450:19
pure [1] - 3621:7
purely [1] - 3579:11
purpose [17] -
3417:5, 3417:14,
3426:22, 3426:25,
3427:6, 3490:24,
3500:24, 3501:3,
3523:19, 3534:21,
3546:17, 3546:18,
3548:6, 3564:15,
3583:9, 3597:14,
3616:10
purposely [1] -
3600:10
purposes [5] -
3410:23, 3413:7,
3415:17, 3467:6,
3558:10
push [4] - 3453:4,
3488:3, 3506:13,
3526:17
pushes [1] - 3526:4
pushing [1] - 3423:3
put [49] - 3389:2,
3397:7, 3404:18,
3411:4, 3411:9,
3413:5, 3415:1,
3417:3, 3420:8,
3431:12, 3431:22,
3442:20, 3451:18,

3464:14, 3477:7,
3481:16, 3489:18,
3490:25, 3499:11,
3499:25, 3506:8,
3516:9, 3520:11,
3526:6, 3539:11,
3540:3, 3540:24,
3555:3, 3563:20,
3565:9, 3565:22,
3566:25, 3567:1,
3567:16, 3570:23,
3585:25, 3591:12,
3594:12, 3597:23,
3600:1, 3600:12,
3615:20, 3615:25,
3617:16, 3618:2,
3619:16, 3629:7,
3635:1, 3637:11
putting [12] -
3410:19, 3411:16,
3411:18, 3429:23,
3433:22, 3438:18,
3462:4, 3483:3,
3517:12, 3534:2,
3539:12, 3632:6
PVDF [20] - 3558:22,
3589:10, 3610:18,
3610:19, 3610:23,
3611:2, 3611:3,
3611:4, 3611:19,
3611:24, 3611:25,
3612:2, 3615:6,
3616:5, 3616:24,
3617:13, 3623:3,
3636:13, 3636:14,
3636:16
qualifications [3] -
3386:21, 3386:22,
3632:23
qualified [4] -
3384:8, 3389:22,
3405:10, 3631:4
qualify [1] - 3395:12
qualitative [1] -
3596:24
quality [2] - 3518:10,
3631:13
quantify [1] -
3395:12
questioning [2] -
3408:6, 3528:4
questions [24] -
3410:3, 3412:21,
3412:24, 3413:21,
3413:22, 3414:9,
3415:24, 3416:25,
3472:12, 3472:17,
3483:21, 3491:2,
3492:4, 3507:25,
3508:10, 3508:12,

3520:9, 3547:12,
3615:13, 3622:13,
3635:25, 3641:16,
3641:24, 3642:3
quick [1] - 3613:5
quicker [3] -
3570:16, 3638:20,
3639:8
quickly [2] - 3408:5,
3409:4
quite [17] - 3381:21,
3386:4, 3445:11,
3481:25, 3483:4,
3487:25, 3489:16,
3507:17, 3517:17,
3543:10, 3543:12,
3548:10, 3563:15,
3577:21, 3580:20,
3616:17, 3632:15
quiz [2] - 3508:8,
3541:22
quotes [2] - 3639:2,
3639:4
R&D [4] - 3393:13,
3430:8, 3435:4,
3480:11
raised [2] - 3600:12,
3632:17
ran [1] - 3559:5
Randomized [1] -
3569:9
randomized [2] -
3569:21, 3638:11
range [3] - 3474:18,
3484:7, 3604:6
rank [1] - 3382:3
rapid [2] - 3594:3,
3595:15
rapidly [1] - 3504:21
rat [1] - 3568:10
rate [11] - 3435:25,
3493:24, 3537:5,
3537:8, 3537:9,
3538:7, 3538:25,
3539:1, 3539:2,
3634:17
rates [5] - 3527:13,
3527:19, 3537:21,
3537:22, 3570:18
rather [2] - 3429:1,
3613:14
rats [6] - 3568:3,
3568:9, 3568:14,
3579:16, 3579:18,
3580:5
RCTs [1] - 3538:19
RDR [3] - 3375:23,
3643:4, 3643:15
reached [2] -
3604:24, 3606:11

<p>reacting [3] - 3413:16, 3441:2, 3441:3</p> <p>reaction [30] - 3395:22, 3401:12, 3405:6, 3420:24, 3423:14, 3423:17, 3426:1, 3426:9, 3444:3, 3454:20, 3454:25, 3455:22, 3533:9, 3547:9, 3547:11, 3547:14, 3547:18, 3547:21, 3547:25, 3548:3, 3548:17, 3549:3, 3549:5, 3566:8, 3566:16, 3568:25, 3610:22, 3622:22, 3622:24, 3632:14</p> <p>reacts [2] - 3454:19, 3546:4</p> <p>read [84] - 3465:20, 3469:19, 3504:11, 3505:9, 3506:1, 3506:2, 3507:9, 3507:10, 3507:20, 3507:21, 3508:7, 3508:12, 3508:15, 3508:17, 3509:25, 3510:20, 3511:3, 3511:4, 3511:14, 3512:10, 3516:24, 3516:25, 3517:16, 3518:12, 3518:13, 3521:8, 3521:15, 3521:17, 3522:22, 3522:25, 3523:7, 3535:12, 3541:19, 3542:3, 3543:11, 3543:15, 3549:22, 3554:3, 3554:4, 3555:6, 3566:21, 3569:2, 3570:19, 3570:21, 3571:13, 3571:23, 3581:21, 3583:13, 3585:23, 3585:24, 3587:2, 3587:9, 3587:22, 3594:6, 3594:7, 3595:18, 3595:19, 3596:19, 3601:3, 3603:15, 3604:23, 3606:9, 3607:13, 3609:16, 3620:3, 3620:6, 3621:5, 3622:19, 3622:20, 3623:9, 3623:21, 3626:8, 3626:20, 3626:25, 3627:1, 3627:11, 3627:21, 3629:22, 3629:23,</p>	<p>3638:17, 3640:6</p> <p>readers [1] - 3579:2</p> <p>reading [4] - 3514:15, 3514:21, 3548:23, 3589:25</p> <p>readout [1] - 3537:13</p> <p>ready [2] - 3379:2, 3614:22</p> <p>real [1] - 3473:14</p> <p>reality [1] - 3626:7</p> <p>realize [3] - 3414:22, 3528:14, 3618:9</p> <p>really [17] - 3409:17, 3415:21, 3415:23, 3416:11, 3416:16, 3417:17, 3421:4, 3422:4, 3436:8, 3453:19, 3455:10, 3458:6, 3476:18, 3477:16, 3500:13, 3516:22, 3622:2</p> <p>Realtime [1] - 3643:4</p> <p>reason [15] - 3385:25, 3386:10, 3388:7, 3415:16, 3419:2, 3424:3, 3431:2, 3457:21, 3472:20, 3474:5, 3475:13, 3534:13, 3534:15, 3569:16</p> <p>reasonable [3] - 3427:24, 3428:3, 3488:5</p> <p>reasons [5] - 3413:21, 3425:7, 3525:12, 3526:23, 3527:10</p> <p>received [4] - 3392:7, 3401:15, 3402:8, 3497:4</p> <p>recent [1] - 3523:16</p> <p>recess [3] - 3408:25, 3492:11, 3554:15</p> <p>recipient [1] - 3533:22</p> <p>recitation [1] - 3431:5</p> <p>reclassification [3] - 3598:17, 3601:1, 3603:3</p> <p>recognize [1] - 3444:21</p> <p>recognized [3] - 3398:9, 3457:8, 3481:7</p> <p>recommended [2] - 3518:9, 3581:17</p> <p>reconstructive [3] - 3582:4, 3583:18, 3584:22</p>	<p>record [5] - 3379:15, 3432:10, 3452:12, 3477:24, 3600:15</p> <p>records [1] - 3460:13</p> <p>Recross [1] - 3378:4</p> <p>RECROSS [1] - 3636:2</p> <p>RECROSS- EXAMINATION [1] - 3636:2</p> <p>recurrence [11] - 3435:8, 3512:9, 3516:23, 3526:25, 3527:8, 3527:13, 3537:22, 3570:2, 3570:18, 3633:23, 3634:17</p> <p>recurrences [1] - 3564:22</p> <p>red [2] - 3383:13, 3444:15</p> <p>redirect [1] - 3528:10</p> <p>REDIRECT [2] - 3597:8, 3640:15</p> <p>Redirect [1] - 3378:4</p> <p>reduce [3] - 3421:12, 3422:4, 3426:12</p> <p>reduced [2] - 3421:14, 3422:9</p> <p>reduction [4] - 3422:19, 3449:13, 3455:10, 3581:15</p> <p>refer [3] - 3409:14, 3518:25, 3593:1</p> <p>reference [5] - 3498:19, 3545:13, 3574:11, 3607:12, 3607:14</p> <p>referenced [1] - 3519:16</p> <p>references [2] - 3398:3, 3407:5</p> <p>referred [2] - 3515:24, 3571:7</p> <p>referring [1] - 3409:12</p> <p>refers [1] - 3447:19</p> <p>reflect [1] - 3464:2</p> <p>refute [1] - 3602:23</p> <p>refuted [1] - 3460:6</p> <p>regard [9] - 3385:14, 3413:2, 3417:16, 3429:9, 3456:7, 3465:6, 3468:18, 3535:17, 3579:13</p> <p>regarding [9] - 3400:19, 3425:18, 3440:8, 3461:23, 3472:23, 3484:11, 3598:17, 3602:15,</p>	<p>3607:15</p> <p>regardless [1] - 3622:7</p> <p>regards [4] - 3400:2, 3455:25, 3497:6, 3602:18</p> <p>region [2] - 3606:22, 3607:8</p> <p>registry [9] - 3597:15, 3597:17, 3597:21, 3597:22, 3598:1, 3598:19, 3598:22, 3599:24</p> <p>regrouping [1] - 3598:16</p> <p>regular [1] - 3617:14</p> <p>regular-sized [1] - 3617:14</p> <p>regularly [2] - 3430:10, 3439:20</p> <p>reinforce [1] - 3553:24</p> <p>reinforced [4] - 3509:12, 3509:23, 3510:24, 3511:11</p> <p>reinforcement [3] - 3383:3, 3433:4, 3527:11</p> <p>reiteration [1] - 3451:2</p> <p>relate [6] - 3397:23, 3401:11, 3402:22, 3412:16, 3420:11, 3529:19</p> <p>related [10] - 3398:15, 3445:9, 3452:17, 3471:23, 3491:5, 3491:9, 3547:15, 3551:6, 3589:15, 3590:17</p> <p>relates [2] - 3387:18, 3445:23</p> <p>relating [1] - 3399:5</p> <p>relation [3] - 3467:16, 3470:7, 3489:24</p> <p>relationship [1] - 3394:4</p> <p>relative [1] - 3417:9</p> <p>relevance [1] - 3479:21</p> <p>relevant [3] - 3529:21, 3529:23, 3601:2</p> <p>reliable [3] - 3510:19, 3596:15, 3624:10</p> <p>rely [1] - 3524:4</p> <p>remain [1] - 3605:17</p> <p>remains [2] - 3445:4,</p>	<p>3505:6</p> <p>remember [28] - 3432:21, 3449:10, 3498:1, 3518:19, 3519:15, 3533:8, 3533:12, 3540:5, 3540:6, 3541:24, 3551:25, 3556:8, 3558:24, 3561:2, 3567:1, 3573:12, 3609:22, 3619:16, 3619:21, 3621:15, 3622:17, 3624:1, 3629:10, 3636:20, 3637:25, 3638:21, 3641:6, 3641:8</p> <p>remodeling [1] - 3445:5</p> <p>remove [12] - 3444:22, 3445:20, 3462:7, 3629:5, 3630:8, 3630:19, 3630:21, 3632:18, 3632:19, 3632:22, 3633:2, 3633:5</p> <p>removed [2] - 3587:7, 3617:11</p> <p>rendered [1] - 3495:2</p> <p>reoperation [1] - 3634:21</p> <p>reorient [2] - 3432:15, 3586:17</p> <p>reoriented [1] - 3516:13</p> <p>rep [1] - 3418:11</p> <p>repair [39] - 3386:6, 3400:19, 3495:21, 3496:3, 3496:6, 3496:10, 3496:16, 3500:15, 3501:17, 3502:6, 3504:8, 3505:2, 3512:3, 3516:17, 3521:22, 3522:11, 3523:13, 3532:4, 3535:9, 3544:25, 3551:18, 3564:23, 3566:20, 3569:10, 3578:21, 3595:6, 3595:22, 3597:18, 3614:3, 3615:1, 3630:11, 3630:12, 3630:13, 3631:1, 3631:6, 3633:15, 3633:17, 3634:10, 3636:15</p> <p>repairing [2] - 3537:11, 3633:12</p> <p>repairs [3] - 3505:24, 3505:25, 3521:25</p>
---	--	---	---	--

<p>repeated [3] - 3447:20, 3450:12, 3452:10</p> <p>repeatedly [1] - 3411:10</p> <p>repeating [2] - 3472:19, 3591:18</p> <p>repeats [1] - 3447:22</p> <p>repetitive [1] - 3416:24</p> <p>rephrase [1] - 3517:18</p> <p>rephrasing [1] - 3438:9</p> <p>replace [4] - 3439:9, 3449:5, 3611:9, 3611:12</p> <p>replaced [1] - 3605:23</p> <p>replacement [1] - 3544:11</p> <p>report [23] - 3405:23, 3407:3, 3407:5, 3410:19, 3417:20, 3417:21, 3417:24, 3469:17, 3472:5, 3474:9, 3495:19, 3512:18, 3512:20, 3512:23, 3513:4, 3514:16, 3514:22, 3514:25, 3521:12, 3533:6, 3558:25, 3562:24, 3580:2</p> <p>reported [7] - 3504:7, 3505:24, 3510:19, 3518:2, 3608:3, 3626:10, 3627:12</p> <p>reportedly [1] - 3507:6</p> <p>Reporter [2] - 3643:6, 3643:16</p> <p>reporting [1] - 3484:17</p> <p>reports [5] - 3406:15, 3410:10, 3410:15, 3527:12, 3601:25</p> <p>represent [4] - 3384:1, 3400:2, 3493:3, 3498:24</p> <p>representative [4] - 3414:25, 3418:24, 3419:13, 3419:15</p> <p>represented [4] - 3419:16, 3464:2, 3478:16, 3483:19</p> <p>Representing [5] - 3376:7, 3376:12, 3376:17, 3376:23,</p>	<p>3377:6</p> <p>representing [1] - 3406:7</p> <p>represents [2] - 3454:14, 3466:6</p> <p>reproducible [1] - 3586:24</p> <p>required [2] - 3592:2, 3602:16</p> <p>requirement [4] - 3447:17, 3469:23, 3481:10, 3481:14</p> <p>requirements [17] - 3392:22, 3393:22, 3420:23, 3421:3, 3421:7, 3426:6, 3427:10, 3433:7, 3433:11, 3433:18, 3434:1, 3434:10, 3442:4, 3481:7, 3490:23, 3534:19, 3614:15</p> <p>Research [1] - 3402:5</p> <p>research [21] - 3382:4, 3384:20, 3385:9, 3385:13, 3387:12, 3388:13, 3388:23, 3391:20, 3391:22, 3391:23, 3394:25, 3401:21, 3402:3, 3402:6, 3404:7, 3404:10, 3404:23, 3409:13, 3467:6, 3498:24, 3549:10</p> <p>researcher [4] - 3380:18, 3382:9, 3534:20, 3538:17</p> <p>resection [1] - 3390:16</p> <p>resections [3] - 3390:15</p> <p>reserve [1] - 3405:8</p> <p>residence [2] - 3395:16, 3498:5</p> <p>residency [3] - 3381:9, 3381:14, 3497:12</p> <p>residents [1] - 3381:23</p> <p>resources [4] - 3389:2, 3401:22, 3401:23, 3401:25</p> <p>respectfully [1] - 3538:15</p> <p>response [34] - 3385:14, 3387:11, 3387:14, 3387:19, 3388:15, 3394:7,</p>	<p>3395:1, 3395:13, 3397:5, 3398:17, 3399:6, 3402:14, 3426:10, 3427:12, 3434:15, 3440:11, 3442:14, 3459:8, 3460:21, 3465:22, 3466:3, 3491:6, 3533:22, 3579:14, 3582:3, 3583:6, 3583:11, 3583:20, 3603:3, 3603:10, 3611:1, 3615:6, 3619:5, 3622:16</p> <p>responses [1] - 3396:19</p> <p>responsibilities [3] - 3410:7, 3410:10, 3412:13</p> <p>responsibility [3] - 3390:12, 3390:20, 3410:13</p> <p>responsible [7] - 3381:23, 3381:24, 3389:3, 3389:11, 3390:5, 3443:13, 3443:17</p> <p>rest [8] - 3408:2, 3442:10, 3468:18, 3485:11, 3486:15, 3586:5, 3589:25, 3621:19</p> <p>restitute [1] - 3546:10</p> <p>restrictive [1] - 3634:12</p> <p>result [6] - 3397:1, 3399:7, 3421:1, 3421:23, 3461:8, 3487:9</p> <p>Results [1] - 3517:7</p> <p>results [15] - 3393:24, 3394:3, 3425:10, 3425:11, 3430:11, 3447:20, 3461:3, 3469:16, 3510:19, 3555:23, 3585:19, 3618:10, 3621:19, 3621:23, 3625:16</p> <p>resume [1] - 3492:15</p> <p>retracted [1] - 3470:25</p> <p>retraction [3] - 3435:8, 3435:9, 3437:15</p> <p>retrieval [1] - 3484:18</p> <p>retrospective [1] - 3509:21</p>	<p>return [5] - 3391:15, 3507:7, 3570:16, 3638:20, 3639:9</p> <p>returned [1] - 3391:18</p> <p>review [13] - 3387:14, 3401:6, 3405:22, 3407:1, 3428:7, 3435:3, 3452:18, 3462:11, 3491:8, 3504:7, 3509:21, 3617:4, 3633:8</p> <p>reviewed [16] - 3397:14, 3397:16, 3397:20, 3401:24, 3406:3, 3434:4, 3438:22, 3460:2, 3460:13, 3468:23, 3479:13, 3480:25, 3488:16, 3535:22, 3538:13, 3600:17</p> <p>reviewer [3] - 3384:7, 3400:22, 3401:1</p> <p>revised [1] - 3459:15</p> <p>revision [2] - 3384:7, 3386:2</p> <p>revolution [1] - 3571:18</p> <p>Ridgeland [1] - 3376:21</p> <p>rigid [1] - 3479:4</p> <p>RIKER [1] - 3377:3</p> <p>risk [18] - 3410:10, 3442:18, 3451:5, 3455:21, 3455:25, 3457:14, 3457:18, 3457:20, 3458:20, 3459:21, 3468:21, 3532:18, 3532:21, 3532:23, 3532:25, 3533:3, 3534:10, 3610:5</p> <p>risks [7] - 3410:8, 3410:18, 3414:18, 3532:16, 3534:4, 3534:6</p> <p>road [3] - 3528:23, 3529:11</p> <p>Robinson [3] - 3415:12, 3635:3, 3635:10</p> <p>roll [3] - 3543:20, 3623:25, 3625:4</p> <p>roll-up [3] - 3543:20, 3623:25, 3625:4</p> <p>rolled [2] - 3543:19, 3623:23</p> <p>rolled-up [1] -</p>	<p>3543:19</p> <p>rolling [1] - 3624:23</p> <p>room [4] - 3408:13, 3408:16, 3518:24, 3606:3</p> <p>rooms [2] - 3518:25, 3519:1</p> <p>root [1] - 3463:5</p> <p>rope [6] - 3484:19, 3487:11, 3487:13, 3487:25, 3488:8, 3615:21</p> <p>rope-like [1] - 3484:19</p> <p>roped [1] - 3488:24</p> <p>roping [7] - 3485:5, 3485:7, 3486:3, 3487:8, 3488:18, 3489:13, 3489:14</p> <p>Roseland [1] - 3376:5</p> <p>rough [1] - 3475:7</p> <p>roughly [1] - 3617:15</p> <p>rounding [1] - 3589:4</p> <p>Rousseau [1] - 3469:11</p> <p>routine [1] - 3505:23</p> <p>row [1] - 3606:3</p> <p>rule [3] - 3418:9, 3477:16, 3600:18</p> <p>ruler [2] - 3463:13, 3463:24</p> <p>rulings [1] - 3416:20</p> <p>running [9] - 3573:7, 3613:15, 3616:20, 3617:21, 3617:24, 3618:19, 3618:23, 3619:1, 3619:24</p> <p>rupture [2] - 3474:22, 3483:15</p> <p>sacrificed [3] - 3565:16, 3568:6, 3568:18</p> <p>sacrificing [1] - 3579:18</p> <p>safe [15] - 3416:15, 3424:10, 3428:11, 3428:15, 3434:14, 3441:18, 3442:25, 3457:7, 3485:17, 3510:25, 3529:25, 3620:20, 3628:11</p> <p>safely [4] - 3428:17, 3428:23, 3465:2, 3621:18</p> <p>safety [5] - 3426:23, 3427:7, 3427:12, 3485:17, 3626:4</p> <p>salary [3] - 3494:8,</p>
---	--	---	--	--

3494:10, 3494:18
Samon [1] - 3623:21
samples [2] -
 3568:3, 3611:24
sampling [3] -
 3583:17, 3584:10,
 3584:16
satisfactory [3] -
 3585:22, 3639:18,
 3639:23
saw [24] - 3387:23,
 3424:11, 3454:5,
 3460:13, 3460:19,
 3467:22, 3475:20,
 3479:15, 3484:9,
 3489:14, 3491:9,
 3529:4, 3541:16,
 3549:7, 3568:13,
 3605:18, 3606:23,
 3607:3, 3610:21,
 3614:8, 3615:25,
 3617:8, 3625:12,
 3637:3
scar [77] - 3386:8,
 3422:1, 3423:3,
 3424:4, 3424:7,
 3424:13, 3425:1,
 3429:5, 3429:6,
 3429:8, 3434:14,
 3444:25, 3445:7,
 3445:18, 3445:19,
 3446:21, 3446:22,
 3447:1, 3447:5,
 3447:10, 3448:6,
 3448:14, 3448:18,
 3453:1, 3453:6,
 3454:21, 3455:2,
 3455:8, 3455:11,
 3455:15, 3455:16,
 3455:19, 3455:25,
 3456:19, 3456:21,
 3457:1, 3457:4,
 3458:8, 3458:20,
 3461:5, 3461:7,
 3461:24, 3462:7,
 3470:18, 3470:20,
 3470:21, 3471:2,
 3471:22, 3471:24,
 3479:4, 3481:22,
 3485:14, 3533:15,
 3544:3, 3544:4,
 3566:5, 3566:8,
 3588:17, 3589:3,
 3599:16, 3604:21,
 3605:23, 3606:13,
 3606:14, 3607:4,
 3610:3, 3610:5,
 3617:1, 3617:5,
 3617:6, 3619:9,
 3622:9, 3638:25

scarring [16] -
 3396:20, 3424:25,
 3443:19, 3443:22,
 3445:9, 3445:13,
 3445:16, 3445:17,
 3445:23, 3455:22,
 3456:14, 3457:4,
 3479:3, 3604:18,
 3604:19, 3611:4
scars [1] - 3452:21
SCHERER [1] -
 3377:3
school [5] - 3380:12,
 3380:25, 3381:8,
 3383:11, 3497:4
science [21] -
 3382:9, 3384:16,
 3385:15, 3387:10,
 3388:2, 3389:8,
 3391:6, 3391:23,
 3392:8, 3394:25,
 3397:5, 3398:17,
 3401:12, 3402:14,
 3404:24, 3405:5,
 3408:1, 3460:18,
 3491:6, 3538:16,
 3618:6
Sciences [1] -
 3583:3
scientific [21] -
 3383:10, 3384:4,
 3391:16, 3394:6,
 3394:10, 3398:3,
 3400:23, 3401:9,
 3421:23, 3425:9,
 3426:1, 3426:4,
 3426:8, 3426:15,
 3427:24, 3428:4,
 3450:10, 3459:11,
 3460:6, 3548:10,
 3573:2
scientifically [2] -
 3383:20, 3383:23
scientist [2] -
 3391:21, 3486:8
scientists [1] -
 3398:7
scope [7] - 3413:4,
 3413:6, 3414:21,
 3417:1, 3528:1,
 3529:22, 3629:14
Scott [4] - 3434:24,
 3435:3, 3465:7,
 3469:12
screen [5] - 3500:1,
 3503:7, 3563:20,
 3572:18, 3619:16
scroll [4] - 3512:5,
 3564:9, 3590:7,
 3590:14

seated [5] - 3379:1,
 3379:6, 3379:17,
 3492:14, 3554:22
second [14] -
 3435:12, 3450:22,
 3452:10, 3463:22,
 3467:1, 3541:2,
 3546:11, 3547:6,
 3570:24, 3572:7,
 3585:7, 3601:5,
 3601:6, 3637:25
Second [1] - 3376:5
secondary [1] -
 3570:3
section [4] - 3446:2,
 3446:4, 3449:6,
 3549:15
sections [2] - 3396:9
security [1] -
 3624:10
see [136] - 3387:22,
 3388:18, 3391:1,
 3398:25, 3417:2,
 3419:7, 3419:20,
 3436:3, 3436:4,
 3436:15, 3439:16,
 3439:18, 3440:1,
 3440:7, 3440:14,
 3440:15, 3444:15,
 3445:24, 3446:2,
 3446:10, 3450:13,
 3451:25, 3452:2,
 3454:12, 3454:15,
 3454:23, 3455:5,
 3455:6, 3456:6,
 3456:11, 3456:18,
 3456:20, 3456:21,
 3458:13, 3461:13,
 3462:18, 3463:8,
 3464:11, 3464:15,
 3465:22, 3468:2,
 3470:3, 3473:8,
 3473:20, 3475:17,
 3478:2, 3480:24,
 3482:10, 3482:11,
 3485:18, 3487:1,
 3487:4, 3487:10,
 3488:17, 3488:20,
 3488:23, 3489:19,
 3490:11, 3499:14,
 3499:24, 3501:9,
 3501:15, 3501:23,
 3502:1, 3502:14,
 3503:3, 3503:9,
 3503:13, 3503:23,
 3503:24, 3504:6,
 3505:21, 3506:16,
 3508:11, 3508:20,
 3510:17, 3510:19,
 3510:23, 3511:21,

3513:8, 3517:8,
 3518:1, 3519:10,
 3537:8, 3543:11,
 3543:21, 3544:15,
 3545:15, 3549:24,
 3552:19, 3556:9,
 3556:10, 3557:1,
 3563:21, 3564:8,
 3564:10, 3564:15,
 3564:25, 3565:5,
 3565:6, 3565:7,
 3566:2, 3566:4,
 3568:14, 3568:24,
 3569:25, 3570:10,
 3571:1, 3572:16,
 3575:15, 3579:24,
 3582:8, 3582:21,
 3590:20, 3593:4,
 3594:13, 3594:15,
 3594:16, 3595:3,
 3605:13, 3605:18,
 3606:8, 3607:10,
 3607:14, 3607:21,
 3614:6, 3615:9,
 3616:24, 3620:9,
 3624:19, 3624:25,
 3625:1, 3626:9,
 3641:24
seeing [4] - 3454:10,
 3487:7, 3489:13,
 3622:17
sell [2] - 3450:15,
 3490:15
selling [1] - 3477:13
semiquantitative [1]
 - 3583:21
sending [1] -
 3480:17
sends [2] - 3454:20
sense [2] - 3520:23,
 3543:12
sent [5] - 3395:13,
 3406:2, 3467:9,
 3572:11, 3603:7
sentence [22] -
 3460:16, 3511:8,
 3549:6, 3549:11,
 3550:9, 3550:19,
 3551:9, 3561:7,
 3564:16, 3568:2,
 3585:7, 3586:21,
 3587:4, 3587:12,
 3594:1, 3595:11,
 3606:11, 3623:9,
 3623:13, 3627:3,
 3627:11, 3627:18
sentences [5] -
 3503:12, 3506:4,
 3509:17, 3549:14,
 3578:24

separate [2] -
 3397:11, 3548:8
series [1] - 3503:18
serious [7] -
 3385:20, 3385:23,
 3488:7, 3525:18,
 3525:24, 3526:7,
 3534:19
served [1] - 3402:24
set [1] - 3598:23
setting [2] - 3629:4,
 3639:13
setup [1] - 3479:20
seven [7] - 3383:23,
 3385:13, 3402:21,
 3450:5, 3529:14,
 3538:18, 3593:21
several [10] -
 3381:15, 3389:21,
 3393:11, 3398:12,
 3402:6, 3432:7,
 3527:3, 3560:21,
 3575:19, 3638:14
severe [1] - 3449:14
severely [1] - 3528:3
shape [4] - 3484:19,
 3487:20, 3488:4,
 3554:2
share [1] - 3435:18
sheet [2] - 3519:20,
 3520:1
shift [1] - 3554:7
short [8] - 3408:10,
 3485:22, 3524:23,
 3527:9, 3570:15,
 3626:11, 3627:12,
 3638:19
short-term [2] -
 3626:11, 3627:12
shorten [1] - 3530:4
shortest [1] - 3381:2
show [23] - 3407:22,
 3421:3, 3422:6,
 3423:20, 3427:15,
 3434:9, 3438:21,
 3442:13, 3451:11,
 3452:5, 3460:18,
 3482:9, 3484:9,
 3486:3, 3486:21,
 3486:22, 3486:25,
 3521:13, 3558:10,
 3600:13, 3607:17,
 3616:10
showed [21] -
 3422:22, 3504:10,
 3566:6, 3566:15,
 3568:25, 3594:10,
 3609:15, 3620:17,
 3620:19, 3621:1,
 3622:15, 3623:20,

3626:18, 3626:19,
3627:20, 3637:2,
3638:10, 3639:4,
3639:16, 3641:3
showing [11] -
3386:12, 3431:23,
3442:11, 3442:16,
3464:21, 3482:23,
3506:22, 3599:6,
3600:24, 3608:15,
3624:13
shown [15] -
3384:15, 3443:5,
3445:14, 3599:2,
3602:21, 3603:14,
3618:10, 3619:15,
3620:5, 3620:16,
3621:14, 3623:6,
3625:19, 3636:19,
3637:23
shows [4] - 3450:13,
3478:19, 3578:7,
3581:18
shrank [1] - 3422:22
shrink [4] - 3423:8,
3426:5, 3453:4,
3540:18
shrinkage [40] -
3396:23, 3422:2,
3422:5, 3422:9,
3422:20, 3422:23,
3424:18, 3425:1,
3429:6, 3435:22,
3436:1, 3437:20,
3437:21, 3437:22,
3448:6, 3449:13,
3452:17, 3452:24,
3453:7, 3456:1,
3456:24, 3456:25,
3457:5, 3470:21,
3470:22, 3471:2,
3471:17, 3471:22,
3479:7, 3479:8,
3485:12, 3532:25,
3550:4, 3550:5,
3619:11, 3622:6,
3629:20, 3633:22,
3634:4, 3634:6
shrinking [5] -
3397:2, 3422:18,
3423:2, 3423:11,
3540:10
shrinks [1] - 3422:17
side [4] - 3464:8,
3476:22, 3482:11,
3606:24
sidebar [14] -
3430:17, 3432:12,
3450:4, 3451:15,
3486:1, 3486:18,

3527:24, 3530:12,
3537:18, 3539:8,
3600:5, 3601:12,
3626:17, 3627:8
sides [2] - 3464:9,
3518:25
signatory [1] -
3599:21
signed [2] - 3598:22,
3599:21
significant [9] -
3412:16, 3436:6,
3449:8, 3453:13,
3455:9, 3481:4,
3484:24, 3518:1,
3525:17
significantly [3] -
3422:9, 3456:22,
3571:21
Silastic [1] - 3502:9
silicone [1] -
3502:11
silicone-type [1] -
3502:11
similar [8] - 3381:21,
3489:14, 3489:16,
3577:21, 3580:20,
3609:16, 3618:21,
3635:4
similarities [1] -
3577:18
simple [5] - 3395:7,
3472:8, 3475:14,
3527:7, 3552:23
simplest [1] -
3388:12
simply [5] - 3404:18,
3514:11, 3526:14,
3576:22, 3613:10
simulation [1] -
3476:19
sincerely [1] -
3543:14
single [8] - 3394:8,
3514:9, 3533:24,
3553:3, 3555:11,
3569:21, 3636:6,
3638:12
single-center [2] -
3569:21, 3638:12
sit [1] - 3560:23
sitting [2] - 3407:6,
3548:12
situation [6] -
3445:2, 3445:4,
3547:22, 3621:8,
3625:15, 3628:23
six [8] - 3384:19,
3384:22, 3386:7,
3391:11, 3393:13,

3420:16, 3450:5,
3593:20
size [71] - 3381:11,
3421:14, 3424:6,
3424:8, 3440:20,
3448:8, 3452:19,
3453:22, 3453:23,
3453:25, 3457:3,
3457:12, 3457:13,
3457:22, 3458:4,
3458:12, 3458:13,
3459:6, 3459:16,
3459:24, 3460:1,
3461:8, 3461:11,
3462:13, 3462:20,
3463:6, 3463:18,
3464:16, 3464:18,
3464:25, 3465:16,
3466:11, 3466:15,
3466:17, 3467:14,
3467:18, 3469:1,
3469:12, 3469:18,
3469:23, 3470:2,
3471:2, 3471:21,
3472:24, 3481:1,
3481:10, 3481:13,
3481:15, 3540:19,
3550:12, 3550:13,
3553:2, 3557:21,
3572:21, 3575:11,
3576:5, 3576:16,
3592:2, 3595:12,
3597:3, 3602:5,
3602:6, 3603:15,
3604:24, 3605:4,
3605:9, 3606:11,
3617:10, 3623:11,
3623:12, 3623:15
sized [1] - 3617:14
sizes [22] - 3424:20,
3424:24, 3426:18,
3442:8, 3462:22,
3466:19, 3466:23,
3469:17, 3481:18,
3481:21, 3553:7,
3576:8, 3580:21,
3580:25, 3588:3,
3588:10, 3588:12,
3591:19, 3594:2,
3595:14, 3599:20,
3609:17
skin [4] - 3444:15,
3513:24, 3514:2,
3584:25
skip [1] - 3567:4
SLATER [13] -
3376:3, 3376:4,
3412:20, 3414:16,
3415:9, 3415:12,
3415:20, 3416:18,

3417:11, 3418:20,
3419:7, 3419:21,
3419:25
Slater [3] - 3379:7,
3411:10, 3528:2
slide [30] - 3420:8,
3434:16, 3436:15,
3440:7, 3444:6,
3449:2, 3449:17,
3451:18, 3453:8,
3454:3, 3464:15,
3469:9, 3472:1,
3474:8, 3475:19,
3477:22, 3478:15,
3479:11, 3480:23,
3482:6, 3484:8,
3485:18, 3490:1,
3566:2, 3613:2,
3614:8, 3629:7,
3635:1, 3635:2
slides [1] - 3396:11
small [25] - 3380:1,
3424:11, 3429:1,
3444:21, 3448:1,
3452:19, 3454:18,
3455:1, 3458:15,
3458:24, 3460:11,
3487:23, 3516:22,
3524:22, 3568:25,
3571:22, 3574:8,
3576:7, 3598:7,
3599:16, 3604:4,
3605:19, 3608:24,
3633:23, 3639:25
smaller [12] - 3429:1,
3453:6, 3454:17,
3456:20, 3458:1,
3461:17, 3516:5,
3516:7, 3605:11,
3610:23, 3611:4,
3633:22
smooth [2] - 3386:5,
3632:15
smoother [1] -
3423:23
SNOW [1] - 3376:18
so-called [1] -
3598:7
so.. [3] - 3519:11,
3521:14, 3527:5
Society [3] - 3402:4,
3597:16, 3598:24
Sofradim [3] -
3556:12, 3557:25,
3567:4
Soft [6] - 3466:20,
3469:13, 3512:12,
3515:1, 3515:5,
3577:16
soft [15] - 3380:19,

3386:13, 3387:16,
3393:7, 3395:9,
3395:22, 3396:14,
3404:8, 3457:1,
3514:2, 3588:12,
3588:17, 3609:18
Soft [1] - 3436:2
software [1] -
3473:12
sold [6] - 3491:18,
3491:24, 3492:3,
3512:16, 3515:4,
3522:3
solely [2] - 3430:24,
3431:8
solution [3] -
3502:25, 3622:1,
3625:18
solutions [1] -
3560:7
solve [1] - 3548:23
someone [21] -
3393:1, 3402:10,
3407:12, 3415:18,
3416:9, 3416:21,
3432:2, 3437:21,
3441:7, 3457:2,
3457:6, 3459:23,
3460:19, 3469:21,
3469:24, 3470:24,
3471:4, 3471:19,
3560:4, 3622:6,
3624:12
sometime [2] -
3511:22, 3562:6
sometimes [15] -
3389:6, 3423:18,
3471:15, 3471:16,
3504:12, 3515:24,
3519:18, 3521:2,
3526:2, 3543:9,
3616:19, 3616:20,
3634:22
somewhere [6] -
3403:5, 3406:17,
3407:8, 3494:13,
3498:1, 3594:25
soon [2] - 3408:9,
3601:22
sophisticated [1] -
3479:19
sorry [18] - 3380:14,
3383:6, 3403:12,
3438:11, 3486:21,
3509:4, 3511:13,
3541:14, 3541:18,
3549:22, 3559:1,
3567:15, 3573:10,
3580:8, 3582:19,
3584:25, 3615:23,

3637:15
sort [6] - 3423:23,
 3461:12, 3475:11,
 3500:22, 3565:21,
 3631:8
sound [3] - 3493:13,
 3523:4, 3580:5
sounds [2] -
 3384:12, 3391:17
southern [1] -
 3513:10
space [17] - 3446:15,
 3446:21, 3446:23,
 3446:25, 3466:7,
 3467:20, 3500:5,
 3500:6, 3501:10,
 3502:25, 3506:7,
 3520:1, 3526:14,
 3526:24, 3529:16,
 3530:16, 3634:1
spaces [2] - 3454:16,
 3557:19
speaker [1] -
 3399:19
speaking [2] -
 3407:7, 3423:14
specialist [12] -
 3381:19, 3382:12,
 3382:20, 3382:23,
 3389:15, 3389:22,
 3390:7, 3390:9,
 3390:12, 3390:21,
 3522:14
specialists [1] -
 3633:4
specialties [1] -
 3392:6
specialty [1] - 3631:1
specific [11] -
 3385:8, 3394:11,
 3394:12, 3415:21,
 3421:5, 3490:21,
 3490:22, 3495:3,
 3538:2, 3639:13
specifically [12] -
 3385:14, 3408:1,
 3490:6, 3490:7,
 3490:9, 3490:23,
 3529:4, 3529:17,
 3538:10, 3577:20,
 3616:14, 3638:22
specification [4] -
 3464:16, 3467:7,
 3467:8, 3467:13
specify [1] - 3523:18
speculated [1] -
 3596:25
speculative [1] -
 3612:5
Speedwell [1] -

3377:4
spell [1] - 3379:15
spend [2] - 3402:2,
 3408:2
spent [2] - 3406:23,
 3628:6
spheres [1] -
 3464:11
splinter [3] - 3444:8,
 3444:17, 3445:3
splinters [2] -
 3444:18, 3446:20
split [1] - 3506:7
sponge [2] - 3501:9,
 3501:16
Sponge [1] - 3501:23
sponsors [1] -
 3579:25
spot [4] - 3573:6,
 3573:7, 3573:18
Sprague [2] -
 3568:3, 3568:9
Sprague-Dawley [2] -
 3568:3, 3568:9
spreadsheet [1] -
 3636:5
spring [3] - 3487:15,
 3487:24, 3488:9
springing [1] -
 3488:12
Spychaj [2] - 3452:2,
 3629:19
square [7] - 3463:4,
 3463:8, 3463:19,
 3468:3, 3468:4,
 3640:21, 3640:25
squared [2] -
 3462:21, 3516:15
squares [1] -
 3617:14
stability [3] -
 3476:25, 3559:4,
 3617:19
stable [1] - 3610:20
stacks [1] - 3408:14
staining [4] - 3565:7,
 3565:25, 3566:1,
 3566:6
stainings [2] -
 3396:7, 3396:8
stainless [2] -
 3500:17, 3500:25
stand [7] - 3411:15,
 3411:17, 3413:5,
 3415:1, 3418:14,
 3492:15, 3530:5
standard [5] -
 3390:10, 3465:17,
 3466:14, 3610:10,
 3616:15

standardized [2] -
 3596:21, 3616:23
standing [2] -
 3548:12, 3624:12
standpoint [2] -
 3445:25, 3490:10
stands [1] - 3457:6
start [13] - 3379:2,
 3383:11, 3383:20,
 3402:1, 3413:10,
 3433:2, 3481:16,
 3538:19, 3542:5,
 3553:20, 3562:4,
 3562:5, 3597:11
started [18] -
 3380:12, 3380:25,
 3381:9, 3381:14,
 3383:10, 3383:22,
 3385:4, 3385:17,
 3393:5, 3395:9,
 3395:21, 3459:1,
 3498:4, 3502:19,
 3586:10, 3590:6,
 3601:21, 3610:14
starting [1] - 3562:11
state [5] - 3379:14,
 3427:22, 3441:12,
 3460:7, 3577:20
State [1] - 3643:6
statement [8] -
 3430:20, 3441:18,
 3442:18, 3443:2,
 3490:9, 3521:10,
 3603:2, 3635:23
States [6] - 3409:21,
 3493:5, 3505:1,
 3513:10, 3522:3,
 3593:17
statistical [1] -
 3626:3
statistics [1] -
 3417:24
status [1] - 3524:10
stay [5] - 3394:18,
 3475:12, 3488:15,
 3528:6, 3560:19
stayed [3] - 3414:6,
 3529:5, 3529:7
stays [1] - 3632:5
steel [4] - 3500:17,
 3500:19, 3500:22,
 3500:25
STENOGRAPHIC [1] -
 3375:3
step [1] - 3383:18
STEVENS [1] -
 3376:18
stick [5] - 3386:22,
 3440:20, 3493:21,
 3493:23, 3548:25

sticky [3] - 3572:15,
 3572:16, 3572:17
stiff [4] - 3386:8,
 3448:15, 3449:1,
 3456:23
still [22] - 3384:19,
 3392:2, 3394:14,
 3435:10, 3437:8,
 3441:2, 3451:24,
 3482:24, 3482:25,
 3495:17, 3500:24,
 3500:25, 3506:16,
 3512:16, 3517:16,
 3593:15, 3593:16,
 3596:14, 3604:20,
 3606:7, 3627:23,
 3631:12
stitch [2] - 3526:16,
 3526:17
stitches [3] -
 3513:11, 3513:13,
 3526:15
stop [7] - 3381:25,
 3396:17, 3436:10,
 3436:11, 3598:12,
 3615:3, 3630:24
stopped [8] - 3423:7,
 3497:18, 3498:5,
 3532:12, 3562:12,
 3562:13, 3562:14,
 3623:13
story [1] - 3524:23
straggling [1] -
 3415:24
straight [1] - 3512:18
strain [22] - 3429:4,
 3470:13, 3475:11,
 3477:6, 3477:7,
 3477:12, 3481:17,
 3489:18, 3489:20,
 3539:20, 3539:21,
 3539:23, 3539:24,
 3586:6, 3586:7,
 3616:11, 3617:20,
 3632:6, 3639:15
strange [1] - 3384:12
STRANGE [1] -
 3377:3
straps [4] - 3484:19,
 3484:21, 3543:18,
 3623:22
street [1] - 3411:8
Street [2] - 3376:10,
 3376:15
stress [8] - 3455:23,
 3462:5, 3477:1,
 3477:19, 3495:21,
 3509:20, 3517:2,
 3587:20
stressed [2] -

3476:21, 3476:23
stretch [3] - 3481:1,
 3481:11, 3481:12
stretchability [1] -
 3616:21
stretched [2] -
 3476:22, 3553:23
stricken [2] - 3625:9,
 3641:18
strict [3] - 3416:19,
 3597:20, 3616:22
strictly [1] - 3528:5
strike [5] - 3394:23,
 3428:20, 3472:10,
 3484:2, 3485:6
string [1] - 3440:18
strong [3] - 3386:6,
 3421:10, 3422:1
stronger [1] -
 3474:23
structural [7] -
 3428:25, 3434:9,
 3455:5, 3462:2,
 3471:25, 3559:4,
 3617:18
structure [14] -
 3443:4, 3455:13,
 3464:3, 3469:5,
 3474:23, 3475:17,
 3485:3, 3489:9,
 3520:22, 3550:8,
 3553:17, 3553:21,
 3560:6, 3617:17
structures [9] -
 3429:10, 3433:10,
 3454:14, 3457:15,
 3474:18, 3474:19,
 3482:13, 3586:25,
 3622:15
struggle [1] -
 3591:18
students [1] - 3384:2
studied [11] -
 3393:6, 3404:19,
 3404:23, 3416:15,
 3447:20, 3456:6,
 3482:22, 3489:24,
 3497:15, 3510:16,
 3580:5
studies [30] -
 3410:11, 3427:15,
 3442:11, 3452:18,
 3455:1, 3475:3,
 3533:19, 3538:19,
 3540:13, 3542:15,
 3559:22, 3587:14,
 3587:15, 3587:18,
 3596:15, 3597:19,
 3611:21, 3615:7,
 3621:12, 3624:14,

3624:22, 3625:1,
3626:10, 3627:3,
3627:12, 3627:13,
3627:14, 3636:15,
3637:23
studiously [1] -
3414:6
study [52] - 3385:4,
3388:11, 3392:22,
3392:23, 3420:19,
3421:3, 3422:5,
3423:19, 3424:5,
3424:15, 3436:10,
3436:11, 3442:2,
3442:5, 3477:20,
3488:7, 3509:18,
3517:4, 3518:6,
3535:20, 3539:4,
3540:11, 3540:21,
3563:9, 3564:15,
3568:13, 3568:14,
3570:8, 3575:22,
3578:25, 3579:6,
3579:25, 3580:4,
3581:17, 3585:11,
3601:16, 3612:14,
3615:3, 3618:11,
3621:1, 3621:13,
3621:14, 3625:17,
3627:22, 3637:24,
3638:4, 3638:5,
3638:7, 3638:9,
3638:15, 3640:23
studying [6] -
3421:18, 3427:11,
3559:23, 3581:8,
3618:6, 3622:10
stuff [6] - 3528:11,
3529:8, 3543:11,
3555:16, 3565:21,
3631:8
subcutaneous [1] -
3568:4
subject [4] -
3418:17, 3499:1,
3499:3, 3544:13
submitted [3] -
3401:2, 3401:7,
3511:22
subscribe [4] -
3511:25, 3535:7,
3538:11, 3582:13
subscribed [1] -
3509:2
subscription [1] -
3582:17
substance [7] -
3386:20, 3394:15,
3502:4, 3502:8,
3502:15, 3502:19,

3502:24
substances [1] -
3500:15
success [4] -
3537:21, 3538:24,
3539:1, 3539:2
successfully [2] -
3384:16, 3402:6
sufficient [14] -
3384:17, 3441:8,
3441:12, 3457:3,
3464:4, 3468:21,
3471:9, 3481:16,
3488:2, 3490:14,
3490:19, 3596:23,
3622:9, 3626:3
suggest [4] -
3409:15, 3514:6,
3520:7, 3585:21
suggesting [1] -
3514:10
suggests [1] -
3409:14
SUI [1] - 3517:2
suitable [2] -
3490:24, 3566:19
Suite [2] - 3376:10,
3376:20
summarized [2] -
3425:19, 3425:22
summary [2] -
3453:11, 3535:16
summing [1] -
3581:14
superior [1] -
3636:16
SUPERIOR [1] -
3375:1
supervising [1] -
3391:22
supply [1] - 3605:8
support [2] -
3394:11, 3518:7
suppose [1] - 3413:9
surely [1] - 3405:25
surface [4] -
3440:12, 3443:25,
3575:12, 3581:16
surgeon [20] -
3380:16, 3380:17,
3381:22, 3382:17,
3383:8, 3392:5,
3397:6, 3403:12,
3403:19, 3484:12,
3488:11, 3522:22,
3534:20, 3537:25,
3569:23, 3629:25,
3631:9, 3632:12,
3632:22, 3636:10
surgeons [24] -

3387:22, 3502:5,
3502:19, 3502:24,
3503:14, 3505:1,
3525:13, 3526:2,
3526:13, 3526:23,
3535:23, 3552:13,
3576:21, 3589:24,
3590:1, 3590:5,
3593:8, 3594:2,
3597:25, 3618:7,
3633:19, 3634:23,
3637:20, 3639:19
surgeries [7] -
3382:18, 3382:22,
3501:17, 3523:6,
3528:18, 3530:16,
3532:7
Surgery [8] - 3499:7,
3499:17, 3564:3,
3564:7, 3564:10,
3564:11, 3583:1
surgery [73] -
3381:15, 3381:19,
3382:13, 3382:20,
3384:1, 3390:8,
3390:9, 3390:12,
3390:21, 3390:23,
3390:24, 3395:16,
3398:16, 3401:11,
3403:9, 3403:10,
3403:14, 3405:5,
3413:20, 3450:6,
3450:9, 3450:23,
3485:10, 3495:21,
3495:24, 3496:2,
3497:5, 3497:18,
3497:19, 3497:24,
3498:4, 3498:9,
3498:20, 3498:21,
3499:2, 3499:13,
3506:5, 3506:6,
3506:19, 3506:21,
3507:14, 3523:9,
3528:7, 3528:8,
3532:12, 3538:17,
3551:8, 3551:13,
3564:23, 3566:20,
3578:6, 3582:4,
3583:12, 3583:17,
3583:19, 3584:21,
3584:23, 3585:2,
3585:8, 3585:10,
3589:16, 3590:18,
3592:21, 3593:11,
3601:18, 3613:24,
3629:15, 3629:20,
3629:21, 3632:24,
3633:4, 3635:8
Surgical [2] - 3499:8,
3593:5

surgical [52] -
3381:9, 3382:2,
3382:4, 3382:8,
3385:15, 3387:11,
3387:19, 3388:16,
3388:19, 3389:16,
3389:17, 3389:19,
3389:23, 3390:14,
3391:5, 3391:19,
3391:23, 3392:9,
3393:14, 3394:7,
3395:1, 3397:24,
3398:6, 3399:5,
3402:14, 3402:22,
3404:4, 3404:21,
3404:25, 3405:7,
3411:16, 3420:11,
3426:2, 3426:9,
3432:18, 3440:11,
3442:24, 3446:1,
3491:5, 3491:6,
3497:6, 3500:11,
3507:16, 3507:18,
3521:7, 3523:7,
3532:15, 3595:22,
3612:10, 3628:15,
3635:5
surprised [1] -
3523:16
surprising [1] -
3436:8
surrounded [3] -
3446:12, 3454:24,
3455:19
surrounding [1] -
3423:21
survey [1] - 3504:25
Susan [2] - 3465:13,
3465:15
suspending [1] -
3518:11
sustained [5] -
3601:9, 3603:9,
3620:12, 3628:3,
3641:17
suture [15] - 3393:2,
3440:13, 3440:17,
3440:19, 3441:4,
3443:17, 3446:5,
3500:23, 3505:5,
3512:21, 3513:6,
3513:24, 3513:25,
3514:12, 3520:24
sutures [13] -
3441:9, 3441:15,
3446:3, 3500:24,
3513:9, 3513:13,
3513:18, 3513:21,
3514:15, 3514:16,
3526:15, 3613:7

Sweden [1] - 3583:3
swelling [1] -
3444:14
switch [1] - 3623:3
sworn [1] - 3379:12
symbol [1] - 3573:3
symptomatic [1] -
3511:1
Synthetic [2] -
3552:20, 3592:20
synthetic [6] -
3490:6, 3521:7,
3552:23, 3552:24,
3593:10, 3622:14
system [4] - 3444:9,
3535:10, 3585:9,
3625:20
Systems [1] - 3643:5
table [4] - 3449:16,
3556:19, 3580:7,
3581:2
Table [3] - 3556:7,
3556:8, 3567:1
task [1] - 3597:20
team [4] - 3389:9,
3435:4, 3466:4,
3473:25
teams [2] - 3466:1,
3466:18
Technical [2] -
3381:1, 3381:2
technical [2] -
3465:16, 3545:22
technically [1] -
3415:14
technique [5] -
3435:24, 3437:19,
3517:6, 3569:23,
3586:23
techniques [2] -
3468:20, 3518:10
Technologies [1] -
3593:5
TECHNOLOGIES [1]
- 3375:23
technology [1] -
3612:19
techs [1] - 3494:11
Teflon [1] - 3502:14
ten [8] - 3393:14,
3401:3, 3428:9,
3486:13, 3583:16,
3583:25, 3584:1,
3585:13
Ten [1] - 3585:7
tens [3] - 3428:7,
3524:14, 3525:3
Tension [2] - 3512:2,
3516:16
tension [13] -

3461:13, 3461:19,
3461:22, 3474:13,
3474:15, 3474:17,
3477:17, 3512:7,
3516:21, 3518:7,
3627:21, 3630:18,
3632:1
Tension-free [2] -
3512:2, 3516:16
tension-free [4] -
3512:7, 3516:21,
3518:7, 3627:21
term [16] - 3423:18,
3425:23, 3459:8,
3460:10, 3546:7,
3546:9, 3553:13,
3558:12, 3570:15,
3626:11, 3627:3,
3627:12, 3627:13,
3627:14, 3627:22,
3638:19
terms [17] - 3382:3,
3382:14, 3385:8,
3394:23, 3397:4,
3412:14, 3420:20,
3423:6, 3427:7,
3431:16, 3448:4,
3450:7, 3460:14,
3487:7, 3566:15,
3581:9
test [23] - 3393:3,
3420:23, 3422:3,
3461:4, 3462:13,
3464:10, 3466:10,
3466:14, 3468:12,
3468:16, 3468:24,
3476:17, 3482:1,
3482:12, 3488:7,
3559:5, 3559:7,
3586:12, 3586:19,
3609:19, 3609:20,
3609:25, 3618:2
tested [18] - 3395:23,
3456:3, 3488:17,
3488:22, 3489:1,
3556:11, 3558:14,
3558:16, 3558:17,
3572:1, 3586:12,
3588:19, 3588:20,
3588:21, 3589:6,
3589:7, 3589:8,
3609:21
tester [1] - 3620:4
testified [3] -
3379:12, 3495:6,
3529:24
testify [9] - 3380:8,
3410:14, 3412:7,
3414:24, 3417:1,
3417:21, 3417:22,

3419:1, 3432:2
testifying [3] -
3410:18, 3418:7,
3418:23
testimony [17] -
3386:20, 3413:4,
3415:4, 3416:5,
3416:12, 3416:16,
3416:24, 3428:8,
3431:25, 3432:22,
3462:12, 3486:4,
3555:6, 3555:10,
3609:23, 3620:3
testing [28] - 3454:6,
3460:23, 3461:2,
3461:23, 3470:11,
3476:14, 3479:14,
3483:25, 3489:15,
3490:16, 3516:10,
3516:11, 3551:25,
3555:12, 3556:15,
3557:9, 3557:11,
3557:13, 3557:15,
3558:10, 3563:2,
3577:10, 3577:12,
3580:10, 3599:3,
3615:14, 3617:17
tests [2] - 3393:23,
3621:25
text [1] - 3508:18
textile [20] - 3381:5,
3382:2, 3386:11,
3386:13, 3457:15,
3468:6, 3469:5,
3474:18, 3474:23,
3475:16, 3482:13,
3489:9, 3490:25,
3520:22, 3550:8,
3580:9, 3586:25,
3587:8, 3587:21,
3618:5
Textile [1] - 3560:5
thanked [1] -
3600:13
theirs [1] - 3415:17
themselves [1] -
3415:19
thereafter [1] -
3529:18
therefore [48] -
3382:21, 3382:25,
3388:8, 3389:9,
3391:9, 3392:20,
3393:1, 3395:20,
3402:1, 3421:11,
3422:3, 3424:8,
3439:6, 3441:10,
3442:4, 3453:2,
3453:5, 3457:18,
3458:18, 3459:19,

3461:17, 3470:8,
3475:13, 3475:14,
3476:24, 3483:5,
3490:22, 3546:8,
3546:14, 3547:25,
3548:4, 3548:12,
3597:20, 3598:3,
3599:18, 3610:4,
3610:6, 3611:3,
3612:13, 3612:18,
3618:4, 3618:21,
3622:5, 3626:5,
3628:22, 3631:14,
3633:24, 3634:22
Therefore [2] -
3581:13, 3581:15
thereof [1] - 3450:11
thesis [1] - 3383:16
they've [3] - 3419:15,
3448:2, 3471:5
thinking [2] -
3432:18, 3500:25
third [2] - 3466:24,
3494:17
thousand [1] -
3406:7
thousands [2] -
3396:7, 3428:7
threads [2] -
3513:14, 3513:22
three [26] - 3383:15,
3386:7, 3391:4,
3391:14, 3397:11,
3403:3, 3403:4,
3461:10, 3468:7,
3482:18, 3491:2,
3517:9, 3517:20,
3528:9, 3556:5,
3568:5, 3576:1,
3578:24, 3579:17,
3593:20, 3607:2,
3614:18, 3614:22,
3621:20, 3630:17,
3631:22
three-dimensional
[3] - 3461:10, 3630:17,
3631:22
three-month [2] -
3517:9, 3517:20
throughout [6] -
3422:12, 3426:18,
3456:15, 3468:14,
3505:1, 3513:14
thrust [1] - 3418:1
Thunder [8] -
3611:7, 3611:16,
3611:19, 3612:3,
3612:23, 3614:2,
3615:11
Ti [1] - 3569:16

tie [1] - 3451:7
timeline [1] -
3512:13
TiMesh [16] -
3556:12, 3558:3,
3567:4, 3567:7,
3568:16, 3569:16,
3569:25, 3571:2,
3571:13, 3571:14,
3571:15, 3637:22,
3638:11, 3638:16,
3638:22, 3639:7
timing [1] - 3635:8
tiny [2] - 3606:1,
3640:22
tissue [147] -
3380:19, 3383:15,
3385:14, 3386:9,
3386:14, 3387:10,
3387:14, 3387:19,
3388:15, 3392:9,
3393:4, 3394:6,
3395:1, 3395:22,
3396:10, 3396:11,
3396:14, 3396:24,
3397:5, 3398:17,
3399:6, 3401:12,
3402:14, 3404:9,
3405:5, 3405:6,
3421:4, 3423:17,
3423:21, 3424:13,
3426:1, 3427:11,
3428:12, 3428:18,
3428:24, 3434:13,
3434:15, 3441:1,
3442:10, 3442:14,
3445:7, 3446:16,
3446:17, 3446:21,
3447:1, 3447:11,
3448:11, 3453:1,
3453:6, 3454:19,
3455:2, 3455:11,
3455:14, 3455:16,
3455:19, 3456:19,
3456:21, 3456:22,
3457:1, 3458:10,
3459:7, 3460:21,
3461:5, 3461:8,
3461:25, 3468:17,
3470:18, 3474:22,
3475:5, 3475:7,
3478:25, 3481:22,
3485:14, 3487:13,
3488:1, 3488:14,
3489:8, 3491:6,
3496:6, 3514:3,
3518:11, 3533:15,
3533:21, 3546:12,
3553:24, 3566:8,
3566:16, 3566:18,

3569:1, 3578:9,
3579:14, 3579:19,
3584:19, 3585:1,
3585:2, 3586:13,
3587:6, 3587:7,
3588:4, 3588:12,
3588:17, 3588:18,
3594:5, 3595:17,
3599:16, 3601:17,
3602:16, 3602:19,
3602:24, 3604:10,
3604:11, 3604:13,
3605:4, 3605:7,
3605:16, 3605:20,
3605:22, 3605:23,
3606:7, 3606:13,
3606:14, 3606:16,
3606:17, 3606:18,
3608:4, 3608:13,
3609:18, 3610:5,
3610:25, 3614:4,
3614:5, 3621:19,
3625:14, 3628:20,
3630:5, 3630:19,
3632:4, 3632:7,
3632:13, 3638:25,
3640:24
tissues [13] -
3380:19, 3383:3,
3387:16, 3387:21,
3388:3, 3395:9,
3420:24, 3445:1,
3445:8, 3454:21,
3474:24, 3483:15,
3527:11
titanium [8] -
3569:11, 3569:18,
3569:24, 3570:13,
3571:20, 3621:2,
3621:7, 3638:17
titanium-coated [1] -
3569:11
title [14] - 3383:17,
3384:9, 3384:18,
3384:25, 3385:5,
3499:16, 3512:2,
3540:9, 3544:23,
3569:9, 3575:10,
3578:19, 3582:2,
3595:21
today [20] - 3380:8,
3403:11, 3404:4,
3404:18, 3407:8,
3416:13, 3427:23,
3468:5, 3472:17,
3505:6, 3507:18,
3522:19, 3528:21,
3533:20, 3547:6,
3549:1, 3549:9,
3560:23, 3590:12,

3623:18
together [18] -
 3380:5, 3383:24,
 3395:23, 3397:7,
 3423:4, 3424:22,
 3425:19, 3427:16,
 3429:4, 3446:18,
 3446:19, 3453:3,
 3453:4, 3453:5,
 3553:18, 3560:22,
 3562:10, 3607:3
tomorrow [5] -
 3409:4, 3409:5,
 3416:8, 3635:19,
 3642:4
took [6] - 3385:2,
 3463:14, 3568:18,
 3608:16, 3610:6,
 3639:6
tools [1] - 3496:25
top [15] - 3382:7,
 3382:8, 3382:9,
 3453:17, 3474:12,
 3480:17, 3483:24,
 3486:7, 3510:2,
 3511:20, 3516:14,
 3535:2, 3565:6,
 3589:17, 3613:3
topics [1] - 3381:4
total [8] - 3440:17,
 3454:8, 3463:1,
 3463:2, 3469:13,
 3482:14, 3536:11,
 3595:1
totally [4] - 3520:4,
 3590:21, 3591:5,
 3623:1
toward [5] - 3578:4,
 3580:8, 3581:4,
 3587:25, 3595:10
traditional [1] -
 3518:10
training [6] -
 3380:23, 3395:4,
 3404:3, 3485:20,
 3497:3, 3497:12
Transcript [1] -
 3643:8
TRANSCRIPT [1] -
 3375:3
transcript [2] -
 3414:2, 3643:10
transfer [1] - 3628:13
transits [1] - 3622:23
translate [1] -
 3525:23
transvaginal [5] -
 3535:9, 3582:3,
 3583:6, 3583:11,
 3584:2

trauma [1] - 3612:10
travel [1] - 3406:21
treat [1] - 3514:1
treated [2] - 3494:22,
 3524:4
treatise [2] -
 3410:20, 3417:22
treatises [1] - 3418:2
treatment [4] -
 3509:13, 3510:13,
 3518:9, 3527:12
treats [1] - 3518:8
Trelex [1] - 3591:10
tremendously [1] -
 3435:24
trial [7] - 3407:7,
 3407:8, 3410:24,
 3569:10, 3569:22,
 3638:12
TRIAL [1] - 3375:5
trials [3] - 3538:20,
 3626:1, 3626:6
trick [1] - 3533:5
tricks [1] - 3490:8
tried [5] - 3463:11,
 3463:14, 3500:19,
 3528:5, 3617:9
tries [1] - 3444:9
trip [1] - 3385:3
trocars [1] - 3506:13
trocars [3] - 3496:19,
 3506:11, 3506:12
true [10] - 3392:1,
 3396:21, 3445:14,
 3470:2, 3521:9,
 3539:20, 3539:21,
 3539:22, 3639:21,
 3643:9
try [10] - 3395:20,
 3403:22, 3426:23,
 3426:25, 3438:19,
 3439:9, 3488:6,
 3526:2, 3528:3
trying [16] - 3394:16,
 3404:16, 3409:15,
 3431:16, 3447:23,
 3462:13, 3463:1,
 3463:19, 3514:6,
 3520:7, 3520:8,
 3528:20, 3533:5,
 3624:7, 3631:8,
 3640:18
Trzewik [1] - 3480:16
turn [2] - 3500:13,
 3617:6
turned [1] - 3466:5
turns [1] - 3478:17
TVM [2] - 3437:19,
 3542:15
two [42] - 3390:2,

3390:4, 3399:23,
 3402:17, 3407:6,
 3411:2, 3411:8,
 3416:10, 3416:21,
 3425:11, 3425:16,
 3436:25, 3439:15,
 3439:19, 3444:18,
 3444:20, 3446:3,
 3446:15, 3446:19,
 3530:5, 3537:1,
 3537:3, 3546:6,
 3556:5, 3565:5,
 3569:23, 3570:5,
 3570:18, 3578:23,
 3580:10, 3586:25,
 3588:6, 3593:20,
 3594:20, 3595:1,
 3596:24, 3598:7,
 3600:24, 3601:3,
 3610:19, 3630:16
two-and-a-half [1] -
 3600:24
two-day [1] - 3407:6
two-dimensional [2]
 - 3586:25, 3630:16
two-way [1] - 3411:8
type [12] - 3500:10,
 3502:11, 3503:21,
 3517:2, 3517:3,
 3547:8, 3549:2,
 3568:10, 3574:12,
 3590:20, 3604:13,
 3605:3
Type [1] - 3590:20
typed [1] - 3543:10
types [4] - 3528:8,
 3536:9, 3604:3,
 3634:10
typically [1] -
 3551:17
ultimately [1] -
 3405:23
Ultrapro [9] - 3529:5,
 3531:16, 3539:14,
 3539:18, 3613:6,
 3613:12, 3613:23,
 3614:23, 3626:24
UM [1] - 3572:25
under [25] - 3429:3,
 3440:8, 3440:10,
 3477:5, 3478:17,
 3481:11, 3482:16,
 3495:10, 3511:7,
 3512:6, 3516:9,
 3517:1, 3518:5,
 3550:17, 3565:19,
 3565:23, 3568:19,
 3571:12, 3574:13,
 3574:21, 3575:15,
 3579:20, 3585:6,

3587:20, 3587:25
undergoing [3] -
 3509:22, 3585:8,
 3585:9
underneath [2] -
 3513:3, 3532:6
underwent [5] -
 3511:10, 3583:16,
 3583:18, 3584:9,
 3585:1
unfortunately [1] -
 3529:15
uniaxial [7] -
 3476:14, 3476:21,
 3476:23, 3477:2,
 3483:9, 3483:10,
 3552:2
unit [2] - 3389:19,
 3569:23
United [6] - 3409:21,
 3493:4, 3505:1,
 3513:10, 3522:3,
 3593:17
University [11] -
 3381:1, 3381:2,
 3381:10, 3382:1,
 3382:3, 3388:20,
 3389:17, 3391:10,
 3391:16, 3494:5,
 3494:13
university [3] -
 3391:7, 3494:19,
 3582:14
unless [3] - 3428:4,
 3620:13, 3641:20
unlike [1] - 3570:5
Unmet [1] - 3449:6
unmet [2] - 3453:9,
 3453:11
unprotected [1] -
 3532:5
unravel [2] -
 3440:18, 3440:22
unreasonably [1] -
 3491:17
unrelated [1] -
 3550:8
unsafe [2] - 3433:25,
 3462:1
unsupportable [1] -
 3490:10
up [93] - 3382:13,
 3383:7, 3386:9,
 3389:1, 3389:6,
 3410:20, 3417:3,
 3420:8, 3422:22,
 3433:18, 3445:1,
 3449:11, 3451:18,
 3454:4, 3464:17,
 3483:19, 3488:12,

3498:2, 3499:11,
 3503:7, 3508:1,
 3508:20, 3510:2,
 3510:17, 3511:19,
 3512:5, 3516:14,
 3517:10, 3517:21,
 3525:8, 3526:16,
 3526:18, 3532:11,
 3535:2, 3535:11,
 3536:17, 3539:4,
 3539:11, 3539:12,
 3540:3, 3540:24,
 3543:19, 3543:20,
 3547:11, 3549:15,
 3549:24, 3553:19,
 3555:4, 3560:13,
 3563:13, 3563:20,
 3564:9, 3564:14,
 3565:6, 3566:25,
 3567:1, 3567:16,
 3567:25, 3569:20,
 3570:24, 3572:18,
 3573:21, 3576:18,
 3580:7, 3581:14,
 3585:6, 3585:25,
 3587:13, 3589:17,
 3590:7, 3590:14,
 3594:10, 3594:12,
 3595:10, 3597:17,
 3597:21, 3598:23,
 3600:1, 3600:10,
 3600:12, 3603:18,
 3603:20, 3613:25,
 3623:23, 3623:25,
 3624:12, 3624:23,
 3625:4, 3629:7,
 3630:12, 3635:1
upper [1] - 3474:24
Uri [4] - 3434:17,
 3443:12, 3449:17,
 3452:5
urinary [3] - 3495:21,
 3509:20, 3517:2
urogyn [1] - 3538:12
urogynecologist [3]
 - 3403:18, 3497:9,
 3636:10
urogynecologists
 [4] - 3400:15, 3400:18,
 3404:6, 3538:14
Urogynecology [1] -
 3508:23
urogynecology [1] -
 3582:18
urologist [2] -
 3403:20, 3497:8
urologists [1] -
 3400:13
Urology [8] -
 3511:20, 3511:24,

3516:16, 3535:3,
3582:8, 3582:12,
3582:19, 3583:1
US [3] - 3493:25,
3523:14, 3542:21
usage [3] - 3441:9,
3443:14, 3443:18
Usher [3] - 3503:13,
3504:6, 3505:3
usher [1] - 3503:17
utilized [1] - 3521:6
UWE [2] - 3378:5,
3379:11
Uwe [4] - 3379:9,
3379:16, 3405:4,
3540:13
vagina [3] - 3495:25,
3632:20, 3635:4
vaginal [11] - 3512:2,
3512:3, 3512:8,
3516:17, 3516:23,
3517:4, 3583:16,
3584:10, 3584:16,
3627:21
validate [1] -
3627:23
valuable [1] -
3482:24
value [2] - 3626:5,
3638:15
values [2] - 3478:14,
3585:18
variation [2] -
3470:5, 3553:1
variety [4] - 3458:14,
3458:19, 3462:21,
3500:14
various [10] -
3392:25, 3393:6,
3410:11, 3425:21,
3431:16, 3476:3,
3483:8, 3528:7,
3602:3, 3602:15
varying [1] - 3401:3
vascular [2] -
3594:4, 3595:16
vast [2] - 3528:24,
3528:25
venia [6] - 3383:24,
3383:25, 3384:9,
3385:12, 3387:2,
3387:13
version [1] - 3505:3
versus [4] - 3611:25,
3615:14, 3624:16,
3632:8
vessels [9] -
3588:15, 3588:17,
3592:7, 3605:7,
3605:10, 3605:12,

3605:13, 3605:14,
3606:5
vice [1] - 3390:3
video [1] - 3487:10
videos [2] - 3485:20
videotaped [2] -
3415:9, 3415:13
view [1] - 3471:11
village [1] - 3380:1
visceral [3] -
3390:12, 3390:21,
3390:23
visible [1] - 3562:23
visual [1] - 3465:16
vivo [4] - 3540:10,
3587:14, 3587:18,
3621:8
voir [1] - 3394:14
VOIR [1] - 3379:19
Voir [1] - 3378:6
volume [1] - 3602:18
Vypro [5] - 3559:16,
3560:3, 3560:6,
3614:21, 3614:22
wait [5] - 3409:25,
3417:2, 3419:7,
3422:16, 3462:16
Walji [1] - 3435:13
walking [1] - 3525:4
wall [32] - 3383:4,
3383:5, 3385:19,
3397:24, 3404:22,
3421:11, 3433:15,
3433:19, 3441:15,
3444:12, 3444:23,
3461:9, 3461:19,
3488:10, 3512:3,
3512:9, 3516:17,
3516:23, 3522:16,
3524:5, 3526:4,
3526:8, 3527:2,
3545:18, 3589:16,
3590:18, 3628:22,
3629:3, 3630:20,
3632:12, 3633:6,
3634:1
wants [4] - 3408:8,
3413:8, 3417:3,
3507:25
war [3] - 3518:24,
3519:1, 3519:2
warn [1] - 3417:4
warned [3] - 3415:5,
3417:14, 3437:11
warning [1] -
3418:15
warnings [10] -
3412:25, 3413:2,
3413:8, 3413:12,
3413:14, 3413:17,

3413:19, 3413:21
warranted [1] -
3627:23
water [1] - 3453:2
ways [4] - 3463:13,
3466:9, 3553:7,
3598:18
weave [2] - 3553:1,
3614:4
Weber [2] - 3486:5,
3538:15
website [7] -
3493:11, 3562:17,
3562:18, 3562:21,
3562:25
week [7] - 3399:23,
3444:20, 3454:5,
3460:25, 3472:10,
3472:12
weekend [1] -
3399:25
weeks [1] - 3484:10
weigh [1] - 3490:5
weight [18] - 3422:7,
3458:24, 3515:25,
3565:3, 3569:11,
3570:1, 3570:17,
3576:4, 3578:20,
3579:6, 3579:9,
3579:12, 3580:13,
3581:9, 3608:21,
3613:18, 3613:21,
3617:16
welcome [2] -
3412:2, 3493:4
well-known [1] -
3533:19
West [1] - 3376:10
whereas [2] -
3422:22, 3631:21
white [3] - 3463:2,
3467:16, 3605:25
White [2] - 3592:14,
3592:17
whole [4] - 3394:2,
3504:18, 3542:3,
3577:7
wide [2] - 3506:7,
3633:25
widely [2] - 3521:21,
3521:24
wider [1] - 3640:24
width [2] - 3457:25,
3573:22
WILLIAM [1] -
3376:19
William [1] - 3493:2
william.gage@
butlersnow.com [1] -
3376:22

willing [1] - 3438:18
window [1] - 3525:2
wish [1] - 3500:3
withdraw [3] -
3427:4, 3483:22,
3602:12
withdrawn [1] -
3628:2
withstand [1] -
3476:25
Witness [2] - 3378:4,
3532:1
WITNESS [12] -
3379:16, 3422:21,
3438:3, 3489:6,
3508:2, 3603:6,
3609:8, 3609:10,
3620:11, 3628:22,
3633:3, 3640:6
witness [29] -
3379:7, 3386:16,
3405:10, 3410:22,
3410:25, 3411:20,
3411:21, 3411:23,
3412:6, 3412:8,
3412:14, 3413:5,
3416:22, 3420:5,
3430:19, 3430:23,
3430:24, 3431:4,
3431:8, 3431:9,
3431:10, 3432:2,
3432:3, 3438:1,
3438:4, 3492:15,
3538:24, 3600:20,
3642:6
witnesses [4] -
3406:12, 3411:14,
3416:19, 3539:5
woman [4] -
3439:22, 3439:25,
3488:20, 3584:17
woman's [27] -
3402:16, 3428:12,
3428:17, 3428:24,
3429:23, 3434:12,
3437:14, 3441:11,
3442:9, 3442:25,
3443:10, 3462:1,
3465:2, 3468:17,
3477:13, 3485:8,
3487:2, 3487:19,
3488:25, 3584:18,
3620:21, 3621:18,
3624:24, 3628:20,
3630:4, 3631:23,
3632:19
women [10] -
3491:19, 3511:10,
3517:1, 3517:13,
3517:22, 3536:14,

3584:6, 3585:3,
3585:13, 3639:17
won [4] - 3418:2,
3418:3, 3558:9,
3558:12
wondering [2] -
3394:13, 3407:15
word [1] - 3591:6
wording [1] -
3558:24
words [15] - 3401:6,
3423:12, 3428:1,
3440:12, 3448:2,
3448:3, 3547:17,
3575:18, 3576:23,
3588:20, 3596:10,
3596:12, 3610:25,
3630:2, 3640:10
works [1] - 3622:2
world [10] - 3382:5,
3382:10, 3404:19,
3421:23, 3426:1,
3426:4, 3426:8,
3426:15, 3486:8,
3524:12
worldwide [3] -
3460:2, 3523:15,
3635:2
worse [1] - 3455:24
worth [1] - 3440:23
wound [6] - 3385:20,
3401:13, 3423:9,
3423:24, 3426:11,
3446:20
wounds [3] -
3513:15, 3513:22,
3513:24
woven [3] - 3440:24,
3553:6, 3553:22
wrap [1] - 3628:17
wrapped [1] -
3448:18
wrinkled [2] -
3386:9, 3488:11
write [3] - 3405:23,
3600:25, 3606:6
writing [2] - 3407:2,
3583:5
written [7] - 3398:10,
3410:9, 3420:10,
3458:25, 3466:10,
3466:14, 3576:18
wrote [6] - 3410:19,
3417:20, 3544:20,
3575:5, 3578:1,
3578:15
yards [3] - 3391:18,
3440:21, 3440:23
yarn [1] - 3553:25
yarns [3] - 3552:24,

3553:6, 3554:2
year [41] - 3393:25,
 3395:21, 3401:1,
 3401:4, 3401:6,
 3401:10, 3406:2,
 3406:24, 3437:5,
 3437:19, 3438:15,
 3439:12, 3449:18,
 3450:14, 3451:22,
 3453:9, 3469:11,
 3493:18, 3493:20,
 3494:9, 3494:10,
 3494:18, 3515:2,
 3523:8, 3523:12,
 3523:24, 3524:9,
 3524:18, 3524:19,
 3527:3, 3534:12,
 3543:2, 3551:17,
 3562:4, 3583:18,
 3584:22, 3585:2,
 3593:24, 3594:11,
 3609:4
year-and-a-half [2] -
 3406:2, 3406:24
years [75] - 3383:15,
 3383:23, 3384:14,
 3384:20, 3384:22,
 3385:3, 3385:4,
 3385:13, 3388:13,
 3389:21, 3391:4,
 3391:14, 3394:23,
 3395:4, 3396:5,
 3400:3, 3401:16,
 3402:8, 3404:7,
 3404:19, 3411:2,
 3416:10, 3423:6,
 3423:23, 3425:12,
 3427:14, 3428:8,
 3428:9, 3429:16,
 3431:21, 3433:6,
 3436:25, 3438:19,
 3439:15, 3440:3,
 3441:1, 3441:8,
 3441:14, 3441:15,
 3441:16, 3443:8,
 3447:7, 3447:20,
 3450:16, 3459:25,
 3465:25, 3480:10,
 3480:14, 3480:15,
 3482:18, 3482:22,
 3491:3, 3491:8,
 3498:25, 3507:14,
 3509:22, 3510:6,
 3510:9, 3517:2,
 3522:17, 3529:2,
 3535:11, 3537:4,
 3559:24, 3559:25,
 3560:1, 3562:8,
 3570:18, 3601:16,
 3602:1, 3614:18,
 3614:22, 3614:24

York [2] - 3376:15
yourself [3] - 3497:2,
 3508:9, 3581:7
yourselves [1] -
 3408:5
Zenobia [1] -
 3435:13
zero [3] - 3413:1,
 3474:15, 3478:22
Zhang [1] - 3582:23
Zheng [1] - 3594:15